Quality Assurance Manual

Table of Contents

Quality Assurance Manual

1 GENERAL

1.1 Forensic Examinations and Services

Forensic examinations are performed by the FBI Laboratory to support FBI and other federal, state, local, and foreign investigations as well as intelligence matters. Additionally, FBI Laboratory personnel provide DNA databasing services, participate in ongoing field investigations by assisting with crime scene searches, and provide other scientific and/or technical services as necessary. The FBI Laboratory also provides expert witness testimony. The Handbook of Forensic Services contains a general listing of forensic services offered by the FBI Laboratory.

1.2 Quality System

C. FBI Laboratory staff provide quality forensic services to its customers and to the continued development and improvement of the quality system. The FBI Laboratory quality system ensures functions are performed as intended and conform to the requirements of applicable accrediting body(ies). FBI Laboratory personnel are responsible for ensuring they understand and apply the quality system to their daily activities. [ISO 17020 8.2.1], [ISO 17025 8.2.1, 8.2.3]

D. The FBI Laboratory quality system provides a mechanism for identifying and/or implementing the policies and procedures that support consistent, accurate and reliable forensic products and services. Additionally, the quality system addresses the competence and impartiality of FBI Laboratory personnel. The LAB-100 document is comprised of quality-supporting requirements such as document control, monitoring, and calibration. The LAB-200 document covers the FBI Laboratory evidence/forensic service cycle and is comprised of requirements such as evidence handling, examinations, and reporting. Unit, discipline, and subdiscipline documents supplement the LAB-100 and LAB-200 documents and provide specificity for laboratory activities. [ISO 17020 8.2.1], [A2LA R318 7.1 FI1.1], [ISO 17025 8.2.1, 8.2.2]

E. The FBI Laboratory quality system applies to FBI Laboratory personnel, both FBI employees and contractors, who are responsible for receiving, checking in/inventorying, handling, and/or examining evidence; DNA databasing; reviewing and providing results; providing instrument operations support; developing, modifying, verifying, and validating methods/procedures; providing testimony; and maintaining the quality system. [ISO 17025 6.2.1]

F. The FBI Laboratory quality system demonstrates the consistent achievement of the requirements in ISO/IEC 17020:2012 (ISO 17020), ISO/IEC 17025:2017 (ISO 17025), American Association for Laboratory Accreditation (A2LA) R318, ANSI National Accreditation Board (ANAB) AR 3125, FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, FBI Quality Assurance Standards for DNA Databasing

Laboratories, and American Board of Forensic Toxicology (ABFT) and assures the quality of laboratory results. The FBI Laboratory operates its quality system in accordance with Option A of ISO 17025 and ISO 17020 and addresses all the required elements. [ISO 17020 8.1, 8.1.1, 8.1.2, 8.2.1], [ISO 17025 8.1, 8.1.1, 8.1.2, 8.2.1]

G. FBI Laboratory management is committed to the development, implementation, and continuous improvement of the quality system. This is communicated via policies, the quality system, other written communication such as email, and meetings with FBI Laboratory personnel. Additionally, the annual management review provides for discussions between Executive Management and the Quality Manager regarding the continual improvement of the quality system. With the support of the FBI Laboratory's management and input from personnel, policies and procedures are developed, revised, and implemented as necessary. [ISO 17020 8.2.2], [ISO 17025 8.2.3]
H. All components related to the fulfillment of the accrediting bodies' requirements are included, referenced, or linked to the quality system. [ISO 17020 8.2.4], [ISO 17025 8.2.4]
I. FBI Laboratory personnel have access to the quality system documents and related information necessary for their responsibilities. [ISO 17020 8.2.5], [ISO 17025 8.2.5]
J. The direction and coordination of examinations, to include traditional forensic analysis, on Chemical/Biological/Radiological/Nuclear (CBRN) material and related evidence, is listed on the FBI Laboratory A2LA Scope of Accreditation.
K. The FBI Laboratory ANAB Scope of Accreditation lists the disciplines that are accredited. Additionally, in the FBI Laboratory, cryptology, and illicit business records, are considered disciplines. Furthermore, the FBI Laboratory has defined the following as subdisciplines under the Materials (Trace) discipline on the ANAB Scope of Accreditation: hairs and fibers, general chemistry, paints and polymers, metallurgy, and geology; and under the Fire Debris and Explosives discipline the following are defined as subdisciplines: fire debris, explosives chemistry and explosives/hazardous devices. The use of the term discipline in the FBI Laboratory quality system documents can include subdiscipline.

1.3 Quality System Objectives

The FBI Laboratory quality system objectives are as follows: [ISO 17025 8.2.1, 8.2.2]

- To ensure services and results provided to FBI Laboratory customers are reliable and scientifically sound.
- To formally establish methods of quality assurance within the FBI Laboratory through the implementation of recognized standards.
- To ensure procedures are valid, dependable, reproducible, and are adequate for the intended purpose.
- To ensure the routine operational performance of units, disciplines, and subdisciplines within the FBI Laboratory are monitored.

- To ensure all areas of the quality system are periodically audited to demonstrate that policies and procedures are being followed.
- To maintain quality, impartiality, and integrity.
- To conform to the requirements of the applicable accrediting body(ies).
- To ensure necessary training is provided for personnel to carry out the provisions of the quality system.

1.4 Terms and Definitions

1.4.1 Addressing in Writing

The following words (to include forms of the same word) used in accrediting bodies' requirements or in this document require addressing in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify. [ANAB AR 3125 8.2.1.1]

1.4.2 List of Terms and Definitions

- **1A** - Compilation of records that are serialized in Sentinel. Physical records related to a submission are placed in a *Supporting Documentation Envelope* (7-251).
- **1C** - Records of the same nature as 1A material but are physically too large to be filed in the 1A.
- **Analytical/Interpretive Inconsistency** - A discrepancy of a technical nature identified during performance monitoring, to include the processing and interpretation of data.
- **Analytical/Interpretive Error** - A technical error identified in casework, DNA databasing or performance monitoring.
- **Archived Storage** – A digital or physical location for long-term storage of evidence.
- **Association** - A determination that a relationship exists between individuals and/or objects. [ANAB AR 3125 3.10]
- **Audit** - A systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled [ANAB AR 3125 3.11]
- **Authorization** – Approval to perform specific tasks and/or duties within a discipline and/or subdiscipline and those that support laboratories activities.
- **Blind Verification** - An independent examination of an item(s) of evidence by another authorized examiner who is unaware of the original examiner's conclusion.
- **Calibration** - The adjusting or standardizing of equipment to ensure agreement of a measurement with a reference standard.
- **Case ID** - A unique alphanumeric identification number assigned by the FBI to an investigation.
- **Case Notes** – The record of controls, instruments used, observations made, results of tests performed, charts, graphs, photos, and other records generated by laboratory personnel to support conclusions.

- **Certified Reference Material** – Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. [ANAB AR 3125 3.12]
- **Chain-of-Custody Log (7-243, 7-243a or equivalent in a Laboratory Information Management System (LIMS))** - A chronological record of the handling and storage of items related to a request over which the FBI Laboratory has control.
- **Check-In Notes** - A mechanism to record the items received, including evidentiary and non-evidentiary items, and the container/packaging, and the condition of these items.
- **Common Core Training** - Training topics developed and executed in a consistent manner for FBI Laboratory personnel as applicable.
- **Communication Log (7-245 or equivalent in a LIMS)** – A record of activity or communication related to a case.
- **Competency Test** - The evaluation of a person's knowledge, skills, and/or ability to perform work. [ANAB AR 3125 3.13]
- **Continuing Education** - The mechanism through which a person increases or updates their knowledge, skills, or abilities, reinforces their knowledge, or learns of the latest research, developments, or technology related to their duties.
- **Control** - A test to demonstrate that a procedure worked correctly, and data are valid.
- **Controlled Document** - A document that is issued and distributed in a trackable manner. (See Document)
- **Corrective Action Plan (CAP)** – A plan to eliminate the cause of a detected nonconformity or other undesirable situation adverse to quality and to prevent recurrence. This may include the effect or impact on the quality of work, the integrity of evidence, or the quality of the testimony. This will be recorded on the *Corrective Action Plan* (7-254) form.
- **Corrective Maintenance** - Actions taken on equipment to restore it to proper operation.
- **Customer** - A person or organization that submits evidence to and/or requests the services of the FBI Laboratory. Equivalent to "client" as used in ISO 17020 or "customer" as used in ISO 17025 and ANAB AR 3125.
- **Decision Rule** – A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement [ISO 17025 3.7]
- **Designee** - A person or role designated in writing to perform a task. The designee can be assigned responsibility for that task by the original person or their manager.
- **Deviation** - A planned departure from a requirement(s) that is approved by authorized personnel prior to its occurrence. A deviation can be major or minor depending on the circumstances. (See Deviations)
- **Disagreement** – When personnel come to competing or mutually exclusive opinions (or as defined in a Level 2 document(s) for a given discipline and/or sub-discipline).
- **Discipline** - A major area of activity in forensic science which may appear on a scope of accreditation. [ANAB AR 3125 3.17]

- **DNA Databasing** - The analysis of DNA database samples for entry into the Combined DNA Index System (CODIS) and, if eligible, for upload to the National DNA Index System (NDIS) (e.g., offenders, arrestees, detainees). The term DNA databasing constitutes part of the term "test" as used in this manual, ISO 17025 and ANAB AR 3125.
- **DNA Match Confirmation Letter** - The official notification that presents written confirmation to a caseworking laboratory to communicate the database match and the identity of the person who provided the DNA database sample. A DNA Match Confirmation Letter is not a *Laboratory Report*.
- **Document** - In the FBI Laboratory quality system, this term applies to Level 0, Level 1, Level 2, Level 3, and Level 4 documents.
- **Electronic Communication (EC) (FD-1057)** - A standardized form typically used to record information in Sentinel as an FBI official record.
- **Environmental Conditions** - Any characteristic of the FBI Laboratory facilities that could reasonably be expected to affect or impact the quality of work.
- **Evaluation Elements** - Specific measures that are assessed during a training evaluation.
- **Evidence** - An item submitted for examination(s). (See Secondary Evidence)
- **Examination Plan (7-262)** - A form prepared, or data entry fields completed, that record the anticipated examination(s) of evidence submitted to the FBI Laboratory.
- **Explosive Reference Tool (EXPeRT)** – A LIMS in which TEDAC shares information with the Counter-Improvised Explosive Device (C-IED) community. It is also used for case management of TEDAC Legacy submissions.
- **FBI Laboratory** - In this manual, this term refers to the entity that includes personnel who are responsible for receiving, checking in/inventorying, handling, and/or examining evidence; DNA databasing; reviewing and providing results; providing instrument operations support; developing, modifying, verifying, and validating methods/procedures; providing testimony; and maintaining the quality system. (See LAB-301 and LAB-302)
- **FBI Laboratory File** - Records generated and/or maintained by the FBI Laboratory for a submission.
- **FBI Laboratory Number** - The FBI Laboratory's identifier that is assigned to each case for examination.
- **Follow Up Report** – A *Laboratory Report* generated if a change or addition must be made to the content of a previously issued *Laboratory Report* or to provide additional information pertaining to a completed request for examination.
- **Hazardous Material Evidence** - Any item or agent (biological, chemical, physical, radioactive) which because of its quantity, concentration, or physical or chemical characteristics, has the potential to cause harm to humans, animals, or the environment, either by itself or through interaction with other factors. Also, hazardous materials are defined by the Department of Transportation as materials in shipment that pose risk to health, safety, and property. The materials are classified as being explosive, toxic, flammable, oxidizing, radioactive, or corrosive. (See the FBI Laboratory Safety Manual)

- **i3 Product** – Simplified reporting intended for intelligence, information, and/or investigative leads only and not intended for adjudication purposes.
- **Individual Characteristic Database (ICD)** - A computerized, searchable collection of features generated from samples of known origin from which individual characteristic information originates (e.g., DNA profiles, friction ridge data, or firearm bullet/cartridge case images). [ANAB AR 3125 3.18]
- **Intelligence** - Information specifically tailored to serve as a prelude to a decision or action by law enforcement or intelligence personnel, program managers, executives, or policy makers. In the broadest sense, intelligence is knowledge and foreknowledge of cyber, criminal, or national security threats and issues.
- **Interlaboratory Comparison** - Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. [ISO 17025 3.3]
- **Internal Audit** – An audit conducted by FBI Laboratory personnel to compare the various aspects of the FBI Laboratory's performance with a standard for that performance.
- **Internal Auditor** - A person who conducts Forensic Analysis Support Unit directed audits. In the FBI Laboratory, auditors performing internal audits must successfully complete an approved course.
- **Intralaboratory Comparison** - Organization, performance, and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions. [ISO 17025 3.4]
- **Investigative Lead** – Information provided to a customer intended to advance an investigation.
- **Laboratory Activity** –Testing and sampling performed or directed by FBI Laboratory personnel.
- **Laboratory Examination Request (LER) (FD-1121)** - A Sentinel-based form which may be completed by FBI personnel to request forensic examinations from the FBI Laboratory. (See Request for Examination)
- **Laboratory Report (7-1, 7-1 LIMS)** - An official report that presents case-related information to a customer regarding FBI Laboratory work.
- **Legacy Case** - Evidence or a request for examination submitted to the FBI Laboratory prior to the implementation of the Forensic Advantage (FA) LIMS.
- **Materially Inaccurate Statement in Testimony** - Statement which tends to make any fact at issue before the court more or less likely and may include one that impacts the strength of a person's conclusion.
- **May** - A word used when an element of the quality system is optional or discretionary.
- **Measurand** - Quantity intended to be measured.
- **Measurement** - Process of experimentally obtaining the value of a quantity
- **Measurement Traceability** - Property of a measurement result whereby the result can be related to a reference through a recorded, unbroken chain of calibrations, each contributing to the measurement uncertainty. Also known as metrological traceability or traceability.

- **Measurement Uncertainty** – Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. Also known as uncertainty of measurement.
- **Method** - The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.
- **Must** - A word used when an element of the quality system is required.
- **Nonconformity** – A nonfulfillment of a requirement. (See Nonconformities)
- **Performance Check** - A check carried out at appropriate intervals to verify equipment is working as expected, or to maintain confidence in the calibration status of equipment. Analysis of a control may be used as a performance check.
- **Performance Monitoring** – Processes used to evaluate the ongoing ability of a person and/or the FBI Laboratory to carry out duties reliably.
- **Policy** - A written, standardized, approved communication that defines, contains, or compels action within more than one FBI division or field office.
- **Practicable** – Available and capable of being done after taking into consideration cost, existing technology, and logistics considering overall purpose.
- **Preventive Action** – Action intended to eliminate the cause of a potential nonconformity or other undesirable potential situation.
- **Preventive Maintenance** - Actions taken to ensure instruments and equipment continue to operate properly.
- **Procedure** - A specified way to carry out an activity or a process.
- **Proficiency Testing** - Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons. [ISO 17025 3.5]
- **Proper Seal** - A seal that prevents loss, cross-transfer, or contamination while ensuring attempted entry into the container/package is detectable. These may include a heat-seal, tape-seal, or a lock. A proper seal includes the initials of the person creating the seal being placed on the seal or across the seal onto the container/package, when possible.
- **Qualified** - A term used to identify FBI Laboratory personnel who successfully complete their assigned training program, demonstrate competence, and participate in performance monitoring, when applicable.
- **Quality System** - The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly. Equivalent to "management system" as used in ISO 17025 and ISO 17020 and ANAB AR 3125.
- **Quantity Value** - Property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference.
- **Reagent** - A substance used because of its known chemical or biological activity. [ANAB AR 3125 3.19]
- **Record** - Objective evidence of a condition, work performed, and/or activity conducted.
- **Reference Collection** - Data or materials of known origin or property which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, motor vehicle paints, firearms, ammunition). [ANAB AR 3125 3.20]

- **Reference Material** - Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties. [ANAB AR 3125 3.21]
- **Reference Standard** - Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location. [ANAB AR 3125 3.23]
- **Remediation –** The process used to correct a deficiency of demonstrated competence in an evaluated activity.
- **Request for Examination** – A customer's proposed contract to the FBI Laboratory submitted via a Laboratory Examination Request (LER) (FD-1121), Electronic Communication (EC) (FD-1057), Lead, *Terrorist Explosive Device Analytical Center (TEDAC) Item Submission Form* (7-275), *TEDAC Bulk Submission Form* (7-276), or a letter on agency letterhead. This term may be used when requesting a service that is not considered an examination and does not cover requests for DNA databasing.
- **Request Only** - A request for FBI Laboratory services that does not require the submission of evidence.
- **Resource Manager** - A module in a LIMS for tracking FBI Laboratory equipment and calibration and specified maintenance records. Other recordkeeping software (e.g., Laserfishe, STACS) may be used to perform equivalent functions.
- **Root Cause(s)** - The fundamental reason(s) a nonconformity occurred.
- **Sample Tracking and Control Software (STACS)** - The LIMS that may be used by DNA personnel in lieu of or in addition to the FBI Laboratory's main LIMS.
- **Sampling** - Selection of a sample for testing, according to a procedure. The approach to sampling can be either non-statistical or statistical. [ANAB AR 3125 3.25]
- **Scientific Review Board** - Personnel selected to assist in the resolution of a disagreement of a scientific or technical nature within the FBI Laboratory.
- **Secondary Evidence -** Material derived from an examination process on an item of evidence and recorded on a secondary evidence log. It is not an individual item submitted by a customer and could not have been assigned an item identifier through the evidence breakdown process.
- **Secondary Evidence Log** - A listing of secondary evidence (Level 2 forms may vary slightly in naming of this log).
- **Sentinel** - The FBI's official recordkeeping, information, and case management system.
- **Should** - A word used when an element of the quality system is recommended but not required.
- **Sponsoring Attorney** - Attorney who subpoenaed the witness.
- **Standard Method** - A method that specifies the steps necessary to perform a test, contains documented performance characteristics, and is published by a standards developing organization such as ASTM International. (Formerly known as the American Society for Testing and Materials.)
- **Subdiscipline** – A subcategory of activity in a forensic science discipline and designated as such in the FBI Laboratory.

- **Subject Matter Expert (SME)** - A person having specific skills and/or knowledge of a particular topic derived from training and/or experience.
- **Submission** - Single instance of providing evidence and/or a request for service to the FBI Laboratory.
- **Substantive Violation in Testimony** – Meaningful or significant violation of any requirement related to testimony monitoring (i.e., testimony in conflict with Department of Justice (DOJ) Uniform Language for Testimony and Reporting (ULTRs) or the Approved Standards for Scientific Testimony and Reporting (ASSTR)).
- **Supporting Records** - Technical records not specific to a submission such as calibration and maintenance records, reagent records, and calibration certificates. These records may be retained independent of the FBI Laboratory file.
- **Technical Procedure** - A document that specifies the steps, methods, equipment, and materials necessary to perform a task properly. Technical Procedures are written to provide instruction and standardization for processes influencing laboratory activities.
- **Technical Records** - Accumulations of data and information that support laboratory activities and that indicate whether specified quality or process parameters are achieved. All issued *Laboratory Reports* are retained as technical records.
- **Technical Review** - Evaluation of notes, data and other supporting records that form the basis for the scientific results and conclusions contained in the *Laboratory Report* and/or i3 product. This review consists of determining whether the appropriate examinations have been performed, the conclusions are consistent with the recorded data and are within the scope of the discipline and/or subdiscipline. This term may also be used to describe other reviews (e.g., document preparation).
- **Technical Reviewer** - A competency tested person who is authorized to conduct technical reviews of examination, i3, and/or DNA databasing records in that discipline and/or subdiscipline. For other types of reviews involving technical matters (e.g., documents, validations), a person must have adequate subject matter expertise.
- **TEDAC Case** - A case with examination requests and/or evidence submitted to the FBI Laboratory with the intent of sharing information with the counter-improvised explosive devices (C-IED) community.
- **TEDAC Evidence** - Evidence submitted to the FBI Laboratory with the intent of sharing information with the C-IED community Evidence submitted to the FBI Laboratory with the intent of sharing information with the C-IED community.
- **TEDAC Item Submission Form (7-275)** - A form which may be completed by customers or FBI personnel to request TEDAC examinations when only one case is submitted to TEDAC. (See Request for Examination)
- **TEDAC Bulk Submission Form (7-276)** - A form which may be completed by customers or FBI personnel to request TEDAC examinations when more than one case is submitted to TEDAC. (See Request for Examination)
- **TEDAC Repository** - The location for the long-term retention of TEDAC materials. Items may be eligible for lending to TEDAC partners.

- **Terrorist Explosive Device Analytical Center (TEDAC)** - A section within the FBI Laboratory that performs forensic examinations on IEDs and related material, primarily for intelligence purposes.
- **Training Records –** A collection of records related to a person's training, qualification, and authorization to perform work.
- **Validation** – The process for determining whether specified requirements are adequate for an intended use.
- **Verification** – Provision of objective evidence that a given item fulfills specified requirements (e.g., confirmation of a test result/opinion by performance of the comparison between the unknown and the known by a different person).
- **Verification of Effectiveness** - Confirmation that action steps associated with a Corrective Action Plan have been effective.
- **Verifier** - An examiner who is authorized to conduct verifications.
- **Will** - A word used when an element of the quality system is required.
- **Working Standard** - Measurement standard routinely used to verify measuring instruments or measuring systems.

1.5 Impartiality

A. The FBI Laboratory is committed to performing and managing its laboratory activities in an impartial and structured manner. [ISO 17020 4.1.1], [ISO 17025 4.1.1]
B. FBI Laboratory management is committed to impartiality. [ISO 17020 4.1.5], [ISO 17025 4.1.2]
C. The FBI Laboratory is responsible for the impartiality of its laboratory activities and does not allow commercial, financial, or other pressures to compromise its impartiality. [ISO 17020 4.1.2, 6.1.11], [ISO 17025 4.1.3]
D. FBI Laboratory personnel are committed to good professional practice as documented in the Department of Justice Code of Professional Responsibility for the Practice of Forensic Science. [ISO 17020 6.1.12], [ANAB AR 3125 4.1.3.1.a]
E. FBI Laboratory management ensure the Department of Justice Code of Professional Responsibility for the Practice of Forensic Science is reviewed annually with FBI Laboratory personnel. A record of the review will be maintained. Appropriate actions will be taken when necessary. [ANAB AR 3125 4.1.3.1.b, c]
F. The FBI Laboratory identifies risks to its impartiality on an on-going basis. This includes risks that arise from its activities, from its relationships, or from the relationships of its personnel. [ISO 17020 4.1.3], [ISO 17025 4.1.4]
    1. If a risk to impartiality is identified, FBI Laboratory personnel eliminate or minimize the risk to include requirements described in this document and/or according to FBI policy. [ISO 17020 4.1.4], [ISO 17025 4.1.5]

1.6 Confidentiality

A. The FBI Laboratory is responsible for the management of all information obtained or created during the performance of laboratory activities and maintains confidentiality with its customers. The FBI Laboratory does not place information pertaining to

laboratory activities in the public domain. If this becomes necessary, the customer will be informed in advance. [ISO 17020 4.2.1], [ISO 17025 4.2.1]

B. Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on behalf of the FBI Laboratory, keep all information obtained or created during the performance of laboratory activities confidential, except as required by law. [ISO 17020 6.1.13], [ISO 17025 4.2.4]
C. Information is only released to customers who have a need to know (e.g., customers who submit evidence, case agents, intelligence partners, law enforcement partners, prosecutors) or as required by law (e.g., discovery, Freedom of Information & Privacy Acts (FOIPA)). Customers are not notified of information provided unless the release of confidential information is required beyond the requests typical of a public forensic service provider. [ISO 17020 4.2.2], [A2LA R318 7.4 FI1.5], [ISO 17025 4.2.2]
D. Information received about a customer from sources (e.g., complainant, regulator) other than the customer, will be kept confidential by the FBI Laboratory. The FBI Laboratory also keeps the source of the information confidential, and will not share it with the customer, unless agreed to by the source. [ISO 17020 4.2.3], [17025 4.2.3]
E. FBI *Laboratory Reports* and/or i3 products will contain the applicable warning statements regarding personally identifiable information (PII) and/or information related to juveniles and/or protected identities as described in LAB-200. [FBI Laboratory Executive Management (EM) Directive Redacted]

1.7 FBI Laboratory Organizational Structure

A. The FBI is the principal investigative arm of the United States Department of Justice. The FBI Laboratory is a forensic service provider in the FBI. [ISO 17020 5.1.1], [ISO 17025 5.1]
B. The FBI Laboratory Deputy Assistant Director is the Laboratory Director when specified in the quality system. [FBI Laboratory Assistant Director Directive]
C. The Laboratory Director has overall responsibility for the FBI Laboratory. [ISO 17025 5.2]
D. The Laboratory Director's duties are defined in the FBI Deputy Assistant Director job description. [ANAB AR 3125 5.2.1]
E. The laboratory activities conducted by the FBI Laboratory are defined in its ANAB scope of accreditation and its A2LA scope of accreditation. Additionally, laboratory activities in cryptology and illicit business records conform to FBI Laboratory quality system requirements. [ISO 17020 5.1.3], [ISO 17025 5.3]
F. The FBI Laboratory provides forensic services to meet a customer's request, a submission of evidence, a request to search biometric databases, and/or to confirm a biometric database match. These laboratory activities are conducted in such a way as to conform to the requirements of applicable regulatory authorities and organizations providing recognition (e.g., accrediting bodies). This includes laboratory activities performed at permanent facilities and at other facilities or sites where FBI Laboratory personnel perform forensic services. [ISO 17025 5.4]

G. Personnel performing DNA analysis comply with the National DNA Index System (NDIS) Operational Procedures Manual, the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, and/or the FBI Quality Assurance Standards for DNA Databasing Laboratories, as appropriate. [ANAB AR 3125 Note 5.4]
H. The FBI Laboratory conforms to the requirements in the ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status. [ANAB AR 3125 5.4.1]
I. The FBI Laboratory performs laboratory activities under the authority of 28 Code of Federal Regulations Section 0.85 Subsection G, which is available on the Government Publishing Office website. [ANAB AR 3125 5.4.2]
J. The FBI Laboratory organizational chart shows the structure and the relationships between Executive Management, the Quality Manager, technical operations (i.e., caseworking units, DNA databasing units), and support services. The FBI Laboratory's position in the FBI is shown in the FBI organizational chart. [ISO 17020 5.1.2, 5.2.1, 5.2.4], [ISO 17025 5.5.a]
K. The FBI Laboratory defines the responsibility, authority, and interrelationship of all its personnel who manage, perform, or verify work affecting the results of laboratory activities in the FBI Laboratory organizational chart, unit organizational charts, and appropriate quality system documents. [ISO 17020 5.2.2, 5.2.3], [ISO 17025 5.5.b]
L. The FBI Laboratory has procedures to ensure the consistent application of its laboratory activities and the validity of results. [ISO 17025 5.5.c]
M. The FBI Laboratory provides its personnel the authority and resources needed to carry out their duties including: [ISO 17025 5.6]
    1. Implementation, maintenance, and improvement of the quality system; [ISO 17025 5.6.a]
    2. Identification of deviations from the quality system or from the procedures for performing laboratory activities; [ISO 17025 5.6.b]
    3. Initiation of actions to prevent or minimize such deviations; [ISO 17025 5.6.c]
    4. Reporting to laboratory management on the performance of the quality system and any need for improvement; [ISO 17025 5.6.d]
    5. Ensuring the effectiveness of laboratory activities. [ISO 17025 5.6.e]
N. FBI Laboratory management ensures that:
    6. Communication occurs via email, meetings, or other means regarding the effectiveness of the quality system and the importance of meeting customers' and other requirements. [ISO 17025 5.7.a]
    7. The integrity of the quality system is maintained when changes to the quality system are planned and implemented. [ISO 17025 5.7.b]
O. The FBI Laboratory has available the personnel, facilities, equipment, and support systems necessary to manage and perform its laboratory activities. [ISO 17020 6.1.2], [ISO 17025 6.1]

1.8 Facilities and Environmental Conditions

A. FBI Laboratory permanent facilities are in Quantico, Virginia, and Huntsville, Alabama. Laboratory activities may also be performed by FBI Laboratory personnel at sites away from the permanent facilities, in associated temporary or mobile facilities, or at a customer's facility.

B. Units, disciplines, and/or subdisciplines ensure facilities and environmental conditions are suitable for laboratory activities and do not adversely affect the validity of the results. [ISO 17020 6.2.1], ISO 17025 6.3.1]

C. Any environmental or facility conditions necessary for the performance of laboratory activities are documented in the appropriate technical procedure. [ISO 17020 6.2.3], [ISO 17025 6.3.2]
    1. If environmental conditions influence the validity of results of a laboratory activity, units, disciplines, and/or subdisciplines will monitor, control, and record those conditions as required in a Level 2 procedure. [ISO 17025 6.3.3]

D. Measures to control the FBI Laboratory facilities are implemented, monitored, and periodically reviewed to include:
    1. Access to and use of areas affecting laboratory activities; [ISO 17025 6.3.4.a]
    2. prevention of contamination, interference, or adverse influences on Laboratory activities; [ISO 17020 7.2.4], [ISO 17025 6.3.4.b] and
    3. Effective separation between areas with incompatible laboratory activities. [ISO 17025 6.3.4.c]

E. When laboratory activities are undertaken at sites or facilities other than the permanent FBI Laboratory facilities, personnel will ensure requirements related to facilities and environmental conditions are met. [ISO 17025 6.3.5]

F. Redacted

G. It is the policy of the FBI Laboratory that all personnel, evidence, DNA database samples, and FBI Laboratory files are secure while in FBI Laboratory facilities. [ANAB AR 3125 6.3.4.1]

H. Due to security, classification issues, and the sensitivity of cases, the FBI Laboratory Director restricts access to the FBI Laboratory facilities to only FBI Laboratory personnel, authorized non-FBI Laboratory personnel, and others when escorted by FBI Laboratory personnel. Access to the FBI Laboratory for the purpose of viewing laboratory activities is prohibited. [ISO 17020 6.2.2], [ANAB AR 3125 6.3.4.1]

I. The FBI Laboratory is committed to a safe and healthful work environment and provides policies and procedures regarding health and safety to laboratory personnel in the FBI Laboratory Safety Manual. [ISO 17020 7.1.9]

1.9 Externally Provided Products and Services

The FBI Laboratory ensures the suitability of externally provided products and services affecting laboratory activities when they are intended for incorporation into FBI Laboratory activities, are provided, in part or in full, directly to the customer by the FBI Laboratory, as received from the

external provider; and/or are used to support the operation of the FBI Laboratory. These include: [ISO 17025 6.6.1.a, b, c]

Products	Services
Reference standards	Calibration services
Reference materials	Proficiency tests
Consumable materials	Equipment maintenance
Equipment	Accreditation
	Testing provided by external or contracted entities or subcontractors

1.9.1 Requirements for Externally Provided Products and Services

A. Laboratory procedures for defining, reviewing, and approving externally provided products and services are documented in the Federal and FBI Procurement Policies and Regulations that govern the procurement of products and services from sources external to the FBI. [ISO 17020 6.2.11.a], ISO 17025 6.6.2.a]
B. The FBI Laboratory Financial and Portfolio Management Unit ensures compliance with all Federal, FBI, and divisional budget/accounting policies. [ISO 17020 6.2.11.a], [ISO 17025 6.6.2.a]
C. FBI Laboratory units, disciplines, and/or subdisciplines ensure purchase requests contain adequate information to describe the products and services ordered if they affect laboratory activities. [ISO 17020 6.2.11.a], [ISO 17025 6.6.2.a]
D. The purchase requester and manager(s) approving the request are responsible for ensuring the request meets the necessary quality criteria. [ISO 17020 6.2.11.a], [ISO 17025 6.6.2.a]

1.9.2 Evaluation of External Providers

A. For the purchase of products and services that affect laboratory activities, the FBI Laboratory evaluates external providers based on one or more of the applicable criteria prior to selection: [ISO 17020 6.2.11.a], [ISO 17025 6.6.2.b]
    1. Products or services do not negatively impact the quality of forensic examinations.
    2. Products or services meet characteristics specified in technical procedures (e.g., 95% ethanol).
    3. Services are provided by technically competent personnel.
    4. Products or services have met requirements based on historical data.
    5. Availability, timeliness and/or cost-effectiveness of the product or service.
    6. Recommendations/evaluations from other laboratories.
    7. Calibration services meet the options specified in this document (See Traceability).
    8. Certified reference materials meet the options specified in this document. (See Traceability).

9. Proficiency tests meet the options specified in this document (See Monitoring).
10. Accrediting bodies will be a signatory of the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) multilateral recognition arrangements, demonstrating ISO/IEC 17011 compliance.

B. Purchasing records define items requested to include any specifications (e.g., type, class, grade, precise identification, technical data) necessary for quality forensic examinations. [ISO 17025 6.6.2.c]
C. When the accreditation of providers of products and services must be considered (e.g., calibration services, certified reference materials, proficiency tests), units, disciplines, and/or subdisciplines maintain a list of providers that have been evaluated and approved for use. Records of the evaluations are retained. [ISO 17025 6.6.2.b]
D. The above criteria are also used to monitor and re-evaluate the performance of external providers. [ISO 17025 6.6.2.b]
E. Actions are taken and recorded, when necessary due to evaluations, performance monitoring and re-evaluations. [ISO 17025 6.6.2.d]

1.9.3 Ensuring Conformance of Externally Provided Products and Services

A. Units, disciplines, and/or subdisciplines ensure externally provided products and services conform with specifications defined in the criteria above, the technical procedure, when applicable, and the purchase request prior to their use. [ISO 17020 6.2.11.b], [ISO 17025 6.6.2.c]
B. Units, disciplines, and/or subdisciplines maintain records of demonstrated conformance. [ISO 17025 6.6.2.c]
    1. Validation records can serve as demonstrated conformance for software and equipment.

1.9.4 Communicating Requirements to External Providers

A. Units, disciplines, and/or subdisciplines communicate their requirements to external providers as required by Federal and FBI Procurement Policies and Regulations. [ISO 17025 6.6.3.a]
B. Purchase orders and/or contracts specify the products and services to be provided and when necessary, include:
    1. acceptance criteria; and/or [ISO 17025 6.6.3.b]
    2. required competence of personnel. [ISO 17025 6.6.3.c]
C. The FBI Laboratory communicates its requirements to external providers for activities laboratory personnel, or customers, intend to perform at the external provider's facility (e.g., Hazardous Evidence Analysis Team deployments). [ISO 17025 6.6.3.d]

1.10 Control of Data

A. The FBI Laboratory has access to the data and information needed to perform laboratory activities. [ISO 17025 7.11.1]
B. Each FBI Laboratory LIMS used for the collection, processing, recording, reporting, storage, or retrieval of data is validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) before introduction. Whenever there are any changes, including software configuration or modifications to commercial off-the-shelf software, they are authorized, documented, and validated before implementation. [ISO 17025 7.11.2]
C. Units, disciplines, and/or subdisciplines will have a plan for the validation of computer software developed in-house and retain records of the validation. [ANAB AR 3125 7.11.2.1]
D. Each LIMS:
    1. is protected from unauthorized access; [ISO 17025 7.11.3.a]
    2. is safeguarded against tampering and loss; [ISO 17025 7.11.3.b]
    3. is operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; [ISO 17025 7.11.3.c]
    4. is maintained in such a manner that ensures the integrity of the data and information; and [ISO 17025 7.11.3.d]
    5. includes the recording of system failures and appropriate immediate and corrective actions. [ISO 17025 7.11.3.e]
E. The FBI Laboratory ensures that external providers or operators managing and maintaining a LIMS comply with all applicable requirements of the quality system. [ISO 17025 7.11.4]
F. The FBI Laboratory ensures instructions, manuals, and reference data relevant to the LIMS are readily available to personnel. [ISO 17020 7.1.4], [ISO 17025 7.11.5]
G. Units, disciplines, and/or subdisciplines will ensure calculations and data transfers are checked in an appropriate and systematic manner unless the calculation or data transfer is secure and not subject to human error. [ISO 17020 7.1.8], [ISO 17025 7.11.6], [ANAB AR 3125 7.11.6 Note]
    1. Technical records indicate the check was performed and who performed the check. When possible, the check is not conducted by the person who performed the calculation(s) or data transfer(s). This check may be part of a technical review. [ANAB AR 3125 7.11.6.1]

1.11 Risk/Opportunity/Improvement

A. The FBI Laboratory considers risks and opportunities associated with laboratory activities by: [ISO 17025 8.5.1]
    1. assessing the quality system to ensure it achieves its intended results (see Management Review); [ISO 17025 8.5.1.a]

2. enhancing opportunities to achieve FBI Laboratory objectives and fulfill its purpose (see Management Review); [ISO 17025 8.5.1.b]
3. preventing, or reducing, undesired impacts and potential failures in laboratory activities (see Nonconformities); [ISO 17025 8.5.1.c] and
4. achieving improvement. [ISO 17025 8.5.1.d]

B. FBI Laboratory personnel identify risks and opportunities for improvement and take appropriate actions to include: [ISO 17025 8.5.2.a, b, 8.6.1]:
1. Reviewing quality system documents and technical procedures,
2. Performing validations,
3. Identifying and addressing nonconformities,
4. Assessing recommendations raised during internal audits and external assessments,
5. Considering requested deviations,
6. Implementing preventive actions,
7. Assessing personnel training programs,
8. Performing technical, administrative, and transcript reviews,
9. Participating in proficiency testing, interlaboratory and intralaboratory comparisons,
10. Conducting verifications and blind verifications,
11. Addressing nonconformities,
12. Addressing suggestions and complaints from personnel and customers, and
13. Evaluating the quality system and FBI Laboratory objectives through the annual management review.

C. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results. [ISO 17025 8.5.3]

D. Risks and opportunities related to health and safety are addressed by the Health and Safety Program. [ANAB AR 3125 8.5.1.1]

2 DOCUMENT CONTROL

The documents that comprise the FBI Laboratory quality system are controlled. [ISO 17020 8.3.1], [ISO 17025 8.3.1]

2.1 Document Structure

A. The FBI Laboratory Quality Assurance Manual (LAB-100) and the FBI Laboratory Operations Manual (LAB-200) are the foundational documents of the quality system.

B. Cross-referencing is used within and between documents when possible so that requirements are only stated once.

C. The Laboratory Division hierarchy includes Level 0, Level 1, Level 2, Level 3, and Level 4 documents.

2.1.1 Level 0 Documents (Accreditation, FBI, DOJ, and External Standards/Requirements)

A. ISO 17020, ISO 17025, accrediting body requirements, FBI Laboratory Safety Manual, FBI Policies, and standards/requirements adopted in full (e.g., DNA Quality

Assurance Standards (QAS), applicable Organization of Scientific Area Committees for Forensic Science (OSAC), ASTM, DOJ ULTR) are considered Level 0.

B. Level 0 documents are referenced by their existing name and do not have separate FBI Laboratory document identifiers.
C. Level 0 documents' approvals are completed external to the FBI Laboratory document control process. The approvals for adequacy are performed and documents are issued by the authoritative body.

2.1.2 Level 1 Documents (Laboratory Wide)

A. Laboratory wide requirements and guidance are incorporated into Level 1 documents.
B. LAB-100 contains requirements related to administrative and quality assurance processes.
C. LAB-200 contains requirements related to laboratory activities (i.e., sampling and testing) including the evidence lifecycle/forensic services.
D. The LAB-300 series contains laboratory-wide quick reference guides, style guides, and work instructions when necessary.

2.1.3 Level 2 Documents (Unit, Discipline, Subdiscipline)

A. Unit, discipline, subdiscipline and task specific procedures, administrative procedures, and training manuals are Level 2 documents.
B. Level 2 technical procedures are discipline and/or subdiscipline based where practicable.

2.1.4 Level 3 Documents (Equipment Manuals)

A. Externally produced equipment manuals are Level 3 documents.
B. Level 3 documents are controlled when personnel must follow a procedure within an external document as directed by an FBI Laboratory Level 2 document. [ISO 17020 8.3.2.f]
C. Level 3 documents are referenced by their existing name and do not have separate FBI Laboratory document identifiers. [ISO 17020 8.3.2.f]

2.1.5 Level 4 Documents (Unit/Discipline/Subdiscipline Checklists, Quick Reference Guides, Style Guides, and Work Instructions)

A. Unit, discipline, and/or subdiscipline checklists, quick reference guides, style guides, and work instructions are Level 4 documents.
B. Level 4 documents are controlled by the unit, discipline, and/or subdiscipline following the requirements as outlined in Sections 2.3-2.5.
C. Level 4 documents are for guidance and do not contain requirements.

2.1.6 Units, Disciplines, and/or Subdisciplines Forms

A. Forms capture variable information and, upon completion, are considered records. Checklists used as guides to denote completion of stepwise processes where the information does not vary are not considered forms or records.
B. Automated workflows can be used in lieu of forms. Automated workflow records and system generated records are not considered forms.
C. The use of forms is described in documents. Cross-references to forms can be hyperlinked to the appropriate forms page.

2.1.7 References

A. References for technical procedures are maintained with the validation records. (See Selection, Verification, and Validation of Methods)
B. References are optional in documents and should only be included when all or part of their content is necessary for the understanding of the document.

2.2 Exceptions

A. In certain circumstances exceptions to Level 1 documents may be approved. Exceptions are described in Level 2 documents and reference the Level 1 document where the intentional difference is needed to meet the specific needs of a particular discipline and/or subdiscipline procedure or case type. New or altered exceptions are reviewed and approved by the Quality Manager and the Laboratory Director via the exception workflow.
B. Exception requests will include:
    1. Level 1 Document(s) (document title, rev. # and issue date)
    2. Requirement(s) (clause number and/or the requirement text)
    3. Exception requested
    4. Merits/Risk (pros/cons of why needed)
    5. Scope (who/what the exception applies to)
    6. Requester
    7. Approver(s)
    8. Date(s) of Approval

2.3 Controlled Document Requirements

A. Documents are approved for adequacy prior to issue by authorized personnel as described in Section 2.4. [ISO 17020 8.3.2.a], [ISO 17025 8.3.2.a]
B. Documents are periodically reviewed and updated as necessary as described in Section 2.8. [ISO 17020 8.3.2.b], [ISO 17025 8.3.2.b]
C. Changes and the current revision status of documents are identified as described in Section 2.6.1. [ISO 17020 8.3.2.c], [ISO 17025 8.3.2.c]
D. Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled as described in Section 2.5. [ISO 17020 7.1.4, 8.3.2.d], [ISO 17025 7.2.1.2, 7.2.1.3, 8.3.2.d]

E. Documents are uniquely identified. Level 1 and Level 2 documents are identified according to Section 2.3.1. [ISO 17020 8.3.2.e], [ISO 17025 8.3.2.e]
F. The unintended use of obsolete documents is prevented through restrictive electronic version control or by marking obsolete documents accordingly if they are retained for any purpose. [ISO 17020 8.3.2.g], [ISO 17025 8.3.2.f]

2.3.1 Level 1 and Level 2 Document Identifier Conventions

A. Titles are brief and contain only the procedure name. Document identifiers are only used on Level 1 and Level 2 documents.
B. Documents are identified according to three components.
    1. The first part indicates the source of the document (e.g., LAB). Administrative documents can be assigned to a unit, discipline, and/or subdiscipline, or the laboratory and technical procedures are assigned to the discipline and/or subdiscipline.
    2. The middle numeric portion represents the document type.
    3. The last portion of the document identifier is the revision number.
    4. As an example, LAB-101-01 is a laboratory wide document and it is the first revision.
    5. As an example, GENCHEM-200-02 is a discipline/sub-discipline document and it is the second revision.
C. Guidance for document identifiers can be found in the Document Control Guide.

2.3.2 Styles and Formatting

- The LAB-303 Template will be used for quality assurance procedures.
- The LAB-304 Template will be used for technical procedures.
- The LAB-305 Template will be used for training manuals.

2.4 Approval and Authorization for Documents

Documents	**Approved for Adequacy by**	**Authorized to Issue by**
Level 1 - LAB-100 and LAB-200	Quality Manager	Laboratory Director
Level 1 - LAB-300 Series	Subject Matter Expert	Quality Manager
Level 2	Representative(s) selected by the UC(s) from every affected unit and applicable TL(s) for technical documents.	Laboratory Director
Level 3	Representative(s) selected by the UC(s) from every affected unit.	Not required
Level 4	Representative(s) selected by the UC(s) from every affected unit.	Person(s) authorized by UC(s)

The approver(s) of each Level 1 and Level 2 document records their approval in the document control workflow.

2.4.1 Record Retention

A. Level 1 and Level 2 document approval records are maintained by the Forensic Analysis Support Unit (FASU).
B. Level 3 and Level 4 document approval records are maintained by the issuing unit(s) or applicable support unit.

2.4.2 Routine Prepublication

A. Routine revisions of Level 1 documents are posted as finalized drafts for typically seven calendar days for familiarization and review for non-substantive changes.
B. This prepublication period allows for non-substantive changes (e.g., typos) to be corrected prior to issuance.

2.5 Issuance (Internal Distribution)

A. At a minimum, Level 0, Level 1, and Level 2 documents are posted on Office 365 (O365).
    1. If units, disciplines, or subdisciplines choose to maintain additional controlled copies of documents, a Level 2 document will describe their document control requirements.
B. Level 3 and Level 4 documents are available in a location(s) determined by the unit, discipline and/or subdiscipline controlling a document.

2.5.1 Stakeholder Notification (e.g., briefing, email)

A. Stakeholders are notified on or prior to the issuance date of all new or revised documents.
B. Substantive changes will be communicated in the notification and/or via a briefing.

2.6 Revisions

A master document library is maintained on Office 365 (O365) for Level 1 and Level 2 documents.

2.6.1 Revision History

A. Revision histories of Level 1 and Level 2 documents contain high level, substantive changes.
B. The history can be linked to the section of the document that changed.
C. Level 4 documents are version controlled but revision histories are not required.
D. As Level 0 and Level 3 documents are external to the FBI Laboratory, these documents may not have revision histories.

2.6.2 Archiving

Level 1 and Level 2 archived documents are clearly marked with the effective dates and a watermark.

2.7 External Publication

A. Publicly available documents and applicable validation summaries are posted at https://fbilabqsd.fbi.gov. [Memorandum for Head of Department Components, 2016, justice.gov]
B. Documents requiring redactions for posting on https://fbilabqsd.fbi.gov are indicated as such when they are submitted.
C. The FASU Web Services PM sends those documents specified as needing redactions approximately twice a year to the unit, discipline and/or subdiscipline for marking areas that need to be redacted.

2.8 Annual Document Review

A. The Quality Manager (for Level 1 documents) and applicable Unit Chiefs (for Level 2, Level 3, and Level 4 documents) ensure that each controlled document is reviewed annually and revised when necessary. The TL must participate in the review of any technical documents.
B. This annual review will include checking for conformity to applicable Level 0 documents.
C. A detailed record (i.e., who, when, and what) of the annual review is maintained.
    1. For Level 1 documents, FASU maintains the review record(s).
    2. For Level 2, Level 3, and Level 4 documents, the unit, discipline, and/or subdiscipline maintains the annual review record(s).
    3. A document revision can serve as the annual document review for a document. That revision must be recorded as such on the annual review.

2.8.1 Topics to Review

A. A reviewer(s), as applicable:
    1. Evaluates Level 1 documents to ensure conformance with Level 0 documents.
    2. Evaluates Level 2 documents to ensure conformance with Level 0 and Level 1 documents.
    3. Evaluates relevant OSAC registry standards and determines whether they should be incorporated into Level 2 documents.
    4. Evaluates Level 2 technical documents for accuracy.
    5. Reviews deviation and nonconformity records to incorporate requirements/changes as necessary.
    6. Reviews Level 3 documents for relevance.
    7. Evaluates Level 4 documents for accuracy.

3 WRITING TECHNICAL PROCEDURES (LEVEL 2 DOCUMENTS)

Section headings for technical procedures are listed below 1 and in the Technical Procedure Template. Any sections not listed as required are optional depending on their applicability for the technical procedure.

A. Title (Required)
B. Introduction (Required)
C. Scope (Required)
D. Equipment
E. Standards and Controls
F. Sampling
G. Procedure (Required)
H. Calculations
I. Acceptance Criteria
J. Measurement Uncertainty
K. Limitations (Required)
L. Safety
M. References

4 DEVIATIONS

Deviations to requirements within the quality system will occur only if the deviation has been recorded, technically justified (if appropriate), and approved. By submitting items to the FBI Laboratory, the customer accepts deviations deemed necessary by FBI Laboratory personnel. [ISO 17025 7.2.1.7]

4.1 Evaluation and Selection of Deviation Type

A. Laboratory personnel authorized to perform laboratory activities will evaluate the significance of deviations to determine the appropriate action. [ISO 17020 6.1.3], [ISO 17025 6.2.3]
    1. A minor deviation will be used when a departure from a requirement is needed that is not expected to significantly impact the quality system and applies to a single or finite number of instances at the time requested.
    2. A major deviation will be used when a departure from a requirement is needed that has the potential to significantly impact the quality system and/or is expected to affect multiple instances or be applicable for an extended period of time.
B. Major and minor deviations must be requested and approved prior to departing from the specified requirement(s).
    1. An approved deviation does not eliminate the requirement for validating modifications to existing technical procedures. The approver of the deviation will make the determination if the modification requires validating and will indicate as such on the deviation.

C. Minor deviations will not be used if a document is identified as no longer being fit for purpose.

4.2 Authorized Approvers for Deviations

A. An approver will consider the impact on the quality system and the merits and risks of a deviation before approving.
B. Minor deviation records should be reviewed prior to approval to determine if a major deviation is necessary.

Deviation Approvers

Deviation Type	Approvers - Administrative Nature	Approvers - Technical Nature
Minor	Manager or Technical Leader	Technical Leader*+
Major	Unit Chief(s) and Quality Manager	Technical Leader(s), Unit Chief(s), and Quality Manager

*If the Technical Leader requests a minor deviation of a technical nature, another person qualified and authorized in the same discipline or subdiscipline will serve as the approver.
+ Manager if the work is not in a discipline or subdiscipline.

4.3 Deviation Requests, Approvals, and Records

4.3.1 Major Deviations

A. Major deviation requests will include:
    1. Document(s) (document title, rev. # and issue date)
    2. Requirement(s) (clause number and/or the requirement text)
    3. Deviation requested
    4. Reference to additional validation, if required
    5. Instances/Duration (when the deviation would be applied/how long)
    6. Merits/Risk (pros/cons of why needed)
    7. Scope (who/what the deviation applies to)
    8. Requester
    9. Approver(s)
    10. Date(s) of Approval
B. Major deviation requests and approvals will be recorded in the major deviation workflows.
C. A major deviation will be inactive on the expiration date unless it is renewed.
D. A major deviation can be renewed once for up to 6 months.
E. A major deviation can also be inactivated prior to the expiration date if it is not needed.

4.3.2 Minor Deviations

A. Minor deviation requests will include:
    1. Document(s) (document title, rev. # and issue date)
    2. Requirement(s) (clause # and/or the requirement text)

3. Deviation requested
4. Reference to additional validation, if required
5. Requester
6. Approver(s)
7. Date(s) of Approval

B. Minor deviations will be recorded using a workflow(s), or in unit, discipline, or subdiscipline records to identify trends.

4.4 Deviation Notifications

A. When a major deviation is approved, renewed, or becomes inactive, the requester and the Laboratory Director will be notified.
    1. If the major deviation is applicable to all FBI Laboratory personnel, all personnel will be notified.
B. For minor deviations and major deviations that are not applicable to all FBI Laboratory personnel, the requester will ensure affected personnel are notified.
C. Major deviations can be found with the FBI Laboratory's quality system documents.

4.5 Deviation Disclosures

A. If the Quality Manager determines a major deviation impacts the examination or reporting process, a copy of the approved major deviation will be included in the FBI Laboratory file for each applicable case (e.g., attach to a communication log (7-245 or equivalent in a LIMS) entry, retained in the LIMS, physical copy in the 1A) or the unique identifier of the approved major deviation can be recorded on the appropriate communication log.
B. If the Quality Manager determines a major deviation does not impact laboratory activities or the reporting process, it is not necessary to include or reference the approved major deviation in the FBI Laboratory file.
C. When a minor deviation impacts laboratory activities or the reporting process, the approved deviation will be included in the FBI Laboratory file.
D. For minor deviations not directly impacting laboratory activities or the reporting process, the approved deviation will be maintained by the appropriate unit, discipline or subdiscipline personnel.

4.6 Annual Review of Minor Deviation Records

A. Unit Chiefs will ensure minor deviation records are reviewed annually, at a minimum, to determine what, if any, trends are occurring that may require document revisions.
B. The review of minor deviation records will be recorded and will include a notation as to whether any trends were identified. The name of the reviewer and the date of the review will be recorded.

5 NONCONFORMITIES

A. A nonconformity is the non-fulfillment of a requirement. It can occur when any aspect of laboratory activities or results of the work do not conform to the requirements or when a quality system requirement is not met. FBI Laboratory personnel, internal or external customers, and/or external auditors/assessors may identify a situation or condition where a nonconformity has occurred. [ISO 17020 8.7.4.a], [ISO 17025 7.7.3, 7.10.1.a]
B. All identified nonconformities will be acknowledged by personnel when they are recorded in a centralized location. The records will contain who identified the nonconformity, when it was identified, and what the nonconformity is. Categorization of the nonconformity and actions taken will be recorded once determined. [ISO 17020 8.7.4.a], [ISO 17025 7.10.1.a, 7.10.2, 8.7.3.a, b]

5.1 Initial Assessment of a Nonconformity

A. When a nonconformity occurs, the person identifying the nonconformity will assess the significance of the nonconforming work to determine if any immediate action is needed. Technical management and/or a unit quality assurance representative may be consulted to assist with the evaluation. [ISO 17020 8.7.3, 8.7.4.d, e], [ISO 17025 7.10.1.a, b, c, 8.7.1.a]
B. Immediate action(s) (i.e., containment) may include halting work, halting issuance of results, repeating work, and/or notifying the customer. [ISO 17025 7.10.1.b, e, 8.7.1.a]

5.2 Categorization of the Nonconformity

A. Following the initial assessment, the nonconformity will be categorized as minor or major based on the significance of the nonconforming work based on the Nonconformity Matrix below.
B. The evaluation will consider at least the following:
    1. The impact on the previous results [ISO 17025 7.10.1.c]
    2. The likelihood of recurrence and detection
    3. The acceptability of the nonconforming work [ISO 17025 7.10.1.d]

Nonconformity Matrix

Significance Evaluation		Risk of Repeatability		
		Low likelihood recurrence/ High likelihood detection	Med likelihood recurrence/ Med likelihood detection	High likelihood recurrence/ Low likelihood detection
Impact/ Acceptability	Negligible/ Acceptable	Minor	Minor	Minor
	Moderate/ Acceptable	Minor	Minor	Major
	Severe/ Unacceptable	Major	Major	Major

5.3 Actions to Address a Nonconformity

A. A minor nonconformity will be corrected if practicable. [ISO 17020 8.7.4.c], [ISO 17025 7.10.1.b, d, 8.7.1.a]
B. A minor nonconformity may have action steps to prevent recurrence (i.e., preventive action) (e.g., document revision, deviation, reminder emails, checklists). These steps will be included in the centralized nonconformity records and do not require a *Corrective Action Plan* (CAP) (7-254). [ISO 17020 8.7.2], [ISO 17025 7.10.3, 8.7.1.a]
C. For a major nonconformity, a CAP will be initiated. The affected Unit Chief(s), Technical Leader(s), and the Quality Manager will be notified in writing. [ISO 17020 8.7.3], [ISO 17025 7.10.1.a, b, c, 8.7.1.a]

5.4 Corrective Action Plan – Development

A. When a CAP is initiated for a major nonconformity, it will include reviewing and analyzing the nonconformity; determining the causes of the nonconformity; determining if similar nonconformities exist or could potentially occur; and developing any action steps needed. [ISO 17020 8.7.4.a, b, d, e], [ISO 17025 8.7.1.b, c]
B. A major nonconformity will be recorded on a CAP form and will include: [ISO 17020 8.7.1], [ISO 17025 7.10.3]
    1. A description of the nonconformity(ies), including frequency and/or impact
    2. Any immediate action(s) taken for containment, if applicable
    3. The requirement(s) that is not in compliance
    4. Root cause(s) information
    5. Action steps, corrective and/or preventive, which are specific, measurable, achievable, relevant, and time bound. Action steps will also be proportional to risks and opportunities and include an expected completion date for each action step. The Unit Chief(s) and Technical Leader will authorize the

resumption of work, when necessary. [ISO 17020 8.7.4.e, f], [ISO 17025 7.10.1.f, 8.7.1.c, 8.2.3, 8.7.2], [ANAB AR 3125 8.7.1.g]

6. A plan for the verification of effectiveness (i.e., verification plan) of action steps will be recorded, which specifies the timeframe following the completion of all action steps and the compliance objectives (e.g., acceptable nonconformity rate). There may be instances when a verification plan is not necessary. [ISO 17020 8.7.4.g], [ISO 17025 8.7.1.d]

C. The Quality Manager, applicable Unit Chief(s), and/or Technical Leader(s) will approve a CAP for implementation.
D. Development and approval of a CAP will occur within 45 calendar days of the identification of the nonconformity. Completion of CAP action steps should not exceed 180 calendar days. [ANAB AR 3125 8.7.1.g]

5.5 Corrective Action Plan – Implementation

A. The person managing the CAP (i.e., CAP manager) will ensure each action step is implemented by the expected completion date or request an extension through FASU. The CAP manager will also ensure that objective evidence in support of the completion of each action step is generated and provided to FASU. [ISO 17020 8.7.4.e], [ISO 17025 8.7.1 c]
B. FASU personnel will review the objective evidence and record completion of each action step.

5.6 Corrective Action Plan – Review of Effectiveness and Closing out Corrective Action

A. The CAP manager will ensure that objective evidence demonstrating defined outcome(s) of the verification plan is generated and provided to FASU.
B. FASU personnel will evaluate the effectiveness of a CAP according to the verification plan. [ISO 17020 8.7.4.g], [ISO 17025 8.7.1.d]
    1. If the defined outcome(s) of the verification plan is not met, the Quality Manager will be contacted to discuss and approve additional action steps and a new verification plan. [ISO 17025 8.7.1.e]
    2. If the defined outcome(s) of the verification plan is met, the applicable Unit Chief(s), Technical Leader(s), and Quality Manager will approve the closure of a CAP.
C. FASU will retain CAPs and their associated records. [ISO 17020 8.7.4.f], [ISO 17025 7.10.2, 8.7.3.a, b]

5.7 Preventive Action

A. A preventive action is an action to eliminate the cause of a potential nonconformity. FBI Laboratory personnel may identify a potential nonconformity where a preventive action would be helpful. [ISO 17020 8.8.3.a]
B. Preventive actions can be initiated independent of the preventive action steps initiated to prevent recurrence that are part of the nonconformity process. [ISO 17020 8.8.3.b]

C. Preventive actions will be appropriate to the probable impact of the potential problems. [ISO 17020 8.8.2]
D. Records related to preventive actions independent of the nonconformity process will be maintained by the unit. [ISO 17020 8.8.3.d]

5.8 Centralized Nonconformity Records Risk/Opportunity Review

A. Unit Chiefs will ensure centralized nonconformity records are reviewed at least quarterly.
B. Nonconformities will be reviewed to consider the risks and opportunities associated with the nonconformities to prevent, or reduce, undesired impacts and potential failures in the laboratory activities. [ISO 17025 8.5.c]
    1. When an opportunity or risk is identified, mitigation measures may be performed. Mitigation measures will be recorded. [ISO 17025 8.6.1]
    2. When a risk identifies the need for further action to eliminate the cause(s) of a nonconformity(ies), a CAP will be initiated. [ISO 17025 8.7.1.b]
C. The review of centralized nonconformity records will be recorded and include a notation as to whether any trends were identified, and any actions taken from the review. The name of the reviewer and the date of the review will be recorded. [ISO 17025 7.10.2, 8.6.1, 8.7.1.f, 8.7.3.a, b]

6 PERSONNEL

A. FBI Laboratory personnel, including contract personnel, act impartially, are competent, and work in accordance with the FBI Laboratory quality system. The FBI identifies core competencies for each FBI employee and job-related competencies that are applicable to each FBI job. FBI Laboratory management communicates to personnel their duties, responsibilities, and authorities. [ISO 17020 6.1.4, 6.1.12], [ISO 17025 6.2.1, 6.2.4]
B. Position requirements (e.g., education, work experience, knowledge, skills, and abilities) for hiring personnel are recorded in each FBI position description (FD-243). Selection of personnel follows the guidance put forth by the Merit Promotion and Placement Plan of the Human Resources Division. Records for personnel unit/position assignments are maintained by Laboratory Division Administrative Unit. [ISO 17020 5.2.7, 6.1.5], [ISO 17025 6.2.5.b]
C. Personnel are hired based on their education, knowledge, skills, and abilities (as related to specific job series). Upon entering employment with the FBI Laboratory, personnel will be trained and evaluated to competently perform their job tasks in accordance with their specified unit, discipline and/or subdiscipline Level 2 training manuals. [ISO 17020 6.1.3], [ISO 17025 6.2.3, 6.2.5.a, b]

6.1 Competency Requirements for FBI Laboratory Personnel

6.1.1 Competency Requirements

A. Personnel who perform laboratory activities in the following disciplines and/or subdisciplines must meet the minimum additional educational requirements as follows: [ISO 17020 6.1.1], [A2LA R318 6.1 FI1.1], [ISO 17025 6.2.2], [ANAB AR 3125 6.2.2.1]

Additional Educational Requirements **Discipline/Subdiscipline**	**Minimum Education Requirements**
Fire Debris and Explosives; Geological Materials; Gunshot Residue; Materials (Trace); Seized Drugs; Toxicology	A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.
Biology	A baccalaureate or an advanced degree in a chemical, physical, or biological science. If performing DNA analysis and where applicable, meet the educational requirements of the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories or FBI Quality Assurance Standards for DNA Databasing Laboratories, as appropriate.

B. Specific technical knowledge, skills, and abilities required to competently perform job tasks are identified by subject matter experts and are documented in Level 2 unit, discipline and/or subdiscipline training manuals. [ISO 17020 6.1.1, 6.1.5], [ISO 17025 6.2.2, 6.2.5.a]

6.1.2 Procedures for Determining Competency Requirements

Level 2 training documents will outline the competency requirements for FBI Laboratory personnel as determined by each unit, discipline and/or subdiscipline job duties. [ISO 17020 6.1.1], [ISO 17025 6.2.5.a]

6.1.3 Competency Testing Process for Personnel Who Perform Laboratory Activities

A. In accordance with each unit, discipline and/or subdiscipline training manual, personnel who perform laboratory activities will be competency tested in performing specified work prior to the testing of items. [ISO 17025 6.2.3], [A2LA R318 6.1 FI1.4]

B. Competency testing will cover the spectrum of anticipated tasks related to the specified work. For personnel whose expected job tasks include the review and authorization of results and expressing an opinion or an interpretation, competency testing will also cover those tasks. Successful competency test results must be

achieved prior to performing tasks on evidence or DNA database samples. [ANAB 3125 6.2.3.1], [A2LA R318 6.1 FI1.4]

C. Personnel who perform technical reviews of results or evaluate testimony will also meet the competency test requirements for the tasks being reviewed. [ANAB AR 3125 6.2.3.2], [A2LA R318 7.3 FI1.6.b]

D. Competency tests will be designed and evaluated by a subject matter expert(s).
    1. The Technical Leader for the discipline or subdiscipline will approve the competency test design.
    2. Expected results from the test design will be recorded prior to dissemination of a competency test.
    3. The test design, trainee results, and evaluation will be recorded in the *Competency Tests Design & Reported Results Form* (7-288).
        i. The test design and expected results will be maintained by the unit, discipline and/or subdiscipline.
        ii. The individual competency test results and final evaluation will be maintained in a person's training record.
        iii. If a nonconformity regarding the test design and/or preparations is identified during the evaluation of the trainee's results, the issues concerning the nonconformity will be reviewed and adjudicated by the Technical Leader. This will occur prior to the dissemination of the results to the trainee.

6.2 Training for FBI Laboratory Personnel

Training programs will be created for FBI Laboratory personnel. [ISO 17020 6.1.5], [ISO 17025 6.2.5.c]

6.2.1 Training Manuals

A. Unit, discipline, and/or subdiscipline training manuals for FBI Laboratory personnel will be developed in accordance with a foundation of knowledge, skills, and abilities (KSAs). Training content will contain specific learning objectives that tie directly to job competencies and tasks. [ISO 17020 6.1.1], [ANAB AR 3125 6.2.2.2.a]

B. Each training manual will follow the content and format detailed in the Training Manual Template. The training manuals will identify who the manual applies to, required topics, construction of individual training plans, types of evaluations, and remediation used in that training program. [ANAB AR 3125 6.2.2.2.b, c, d, e, f, g]

C. FBI Laboratory required training topics must be included in Level 2 training manuals as applicable to specific job tasks:
    1. Health/Safety - includes topics: Bloodborne Pathogens, Resource Conservation and Recovery Act (RCRA), and any additional health/safety topics as required. [ANAB AR 3125 6.2.2.2.a]
    2. Communication - includes topics: public speaking, critical thinking, and testimony. [ANAB AR 3125 6.2.2.2.a]

3. FBI Laboratory Common Core Training - includes topics: FBI structure, Laboratory capabilities, quality assurance, evidence handling and control, intelligence overview, and overview of general forensic science. [ANAB AR 3125 6.2.2.2.a, b]
4. FBI Laboratory Legal Training - includes topics: Foundations of the Legal System and Legal Testimony. [ANAB AR 3125 6.2.2.2.d]
5. FBI Laboratory Forensic Ethics - includes topics: Overview of FBI core values, ethical decision-making in forensic science, and expected employee standards of conduct. [ANAB AR 3125 6.2.2.2.c]
6. Real/simulated laboratory activities - includes mentorship, practice/training samples, and competency tests. [ISO 17020 6.1.6b], [A2LA R318 6.1 FI1.2], [ISO 17025 6.2.3], [ANAB AR 3125 6.2.3.1]

6.2.2 Substituting Previous Work Experience

A. Previous work experience may be substituted for portions of a training program as determined by a Technical Leader (or supervisor if the work is not in a discipline or subdiscipline) under the following conditions: [ISO 17020 6.1.7], [ANAB AR 3125 6.2.2.2 Note 1]
    1. A review of a person's work experience and training demonstrate relevance and sufficiency.
    2. A person's current competence on related topics is evaluated in accordance with the unit, discipline or subdiscipline training manual.
    3. Records of the review and evaluation(s) will be maintained in a person's training record.

6.2.3 Laboratory Required Communication Training Milestones for Personnel Who Perform Laboratory Activities

Personnel who perform laboratory activities, in accordance with their assigned role and job tasks, will complete a minimum of one communication exercise per category as designated in the table below.

FBI Laboratory Required Communication Training Milestone Categories for Personnel Who Perform Laboratory Activities

	Public Speaking	Critical Thinking	Moot Court
Forensic Examiner (FE)	x	x	x*
Analyst**	x	x	
*FDDU FEs are excluded from moot court exercises based on their job tasks **Analyst encompasses the following non-examiner roles: chemist, biologist, cryptanalyst, electronics engineer, physical scientist, document analyst			

6.2.3.1 Public Speaking Exercises

A. Public speaking communication exercises support job tasks related to providing briefings, tours, and presentations and are an opportunity for trainees to demonstrate that skill.
B. Public speaking communication exercises can include a unit, discipline and/or subdiscipline capability briefing, a discipline or subdiscipline-defined briefing, or a technical lecture.
C. For each public speaking exercise:
    1. A summary of expectations that contains details such as objectives, topics covered, and associated timeframes will be provided to the trainee and evaluators in advance of the exercise.
    2. Evaluation requirements:
        i. Three evaluators are required for a public speaking exercise using the rubric evaluation method described in section 6.3. The *General Rubric Structures Form* (7-289) must be used.
        ii. One evaluator is required for public speaking exercises that are only evaluated for completion.
        iii. The designated evaluation method will be listed on the summary of expectations and followed in accordance with section 6.3.
    3. The unit, discipline and/or subdiscipline Training Program Manager (TPM) will ensure that the evaluation method is reviewed with the trainee and the evaluators, as appropriate, prior to the public speaking exercise.
D. There will be at least one practice session opportunity afforded to each trainee that includes performance feedback based on the designated rubric evaluation method for the public speaking exercise (does not apply to exercises only evaluated for completion).
E. If the trainee fails to successfully complete a public speaking exercise, the trainee's Unit Chief will be notified in writing and a remediation plan will be developed for the trainee. A second attempt at the same exercise will be conducted after the conclusion of the remediation plan action steps.
F. A unit, discipline, and/or subdiscipline may choose to utilize a practice session as an officially graded exercise if the practice session follows all the evaluation requirements, including the use and retention of applicable records.
G. Completion of the FBI Presentation Skills Course or the Basic Instructor Course are acceptable substitutes for the public speaking training requirement (with approval by Technical Leader). Evaluation records from those courses will be reviewed and approved by the Technical Leader and maintained as part of the person's training records.
H. Records for public speaking exercises will be maintained in a person's training records.

6.2.3.2 Critical Thinking Exercises

A. Critical thinking exercises support job tasks related to communicating technical and scientific concepts to a variety of audiences and are an opportunity for trainees to demonstrate:
    1. recollection and explanation of facts, terms, concepts, technical procedures, and principles of a discipline and/or subdiscipline;
    2. identification, understanding, and defense against criticisms of a discipline and/or subdiscipline, the Laboratory, and/or the FBI;
    3. problem-solving for casework-related and job-related scenarios;
    4. the meaning of and limitations of a discipline and/or subdiscipline and its related conclusions; and
    5. the significance and application of the quality system to their job tasks.

B. Critical thinking exercises can include oral boards, debate teams, written assessments/proposals, and scenario-based or testimony-style exercises.

C. Forensic examiner trainees are required to successfully complete a minimum of one critical thinking exercise identified as an oral board. The *General Rubric Structures Form* must be used.

D. Personnel designated in the analyst category are required to complete a minimum of one critical thinking exercise that aligns with their specified job tasks and is described in their individual training plan.

E. For each critical thinking exercise:
    1. A summary of expectations that contains details such as objectives, topics covered, and evaluation method will be provided to the trainee and evaluators in advance of the exercise.
    2. Evaluation requirements:
        i. Three evaluators are required for each critical thinking exercise using the rubric evaluation method described in section 6.3. The *General Rubric Structures Form* must be used. Evaluators should be subject matter experts in the discipline and/or subdiscipline being evaluated, as applicable.
        ii. The designated evaluation method will be listed on the summary of expectations and followed in accordance with section 6.3.
        iii. If the exercise is an oral board, it will be audio recorded and retained in the person's training records.
        iv. The TPM will ensure that the evaluation method is reviewed with the trainee and the evaluators, as appropriate, prior to a critical thinking exercise.

F. There will be at least one practice session opportunity afforded to each trainee that includes performance feedback based on the designated rubric evaluation method for a critical thinking exercise.

G. If the trainee fails to successfully complete a critical thinking exercise, the Quality Manager will be notified in writing and a remediation plan will be developed for the

trainee. A second attempt at the same exercise will be conducted after the conclusion of the remediation plan action steps.

H. A unit, discipline, and/or subdiscipline may choose to utilize a practice session as an officially graded exercise if the practice session follows all the evaluation requirements, including the use and retention of applicable records.

I. Records for a critical thinking exercise(s) will be maintained in a person's training records.

6.2.3.3 Moot Court Exercises

A. A moot court exercise supports job tasks related to providing expert testimony in a legal setting and are an opportunity for forensic examiner trainees to demonstrate the ability to:
   1. Articulate qualifications as an expert;
   2. Explain facts, terms, concepts, technical procedures, examination processes and principles of a discipline or subdiscipline using lay terms;
   3. Identify, understand, and defend against criticisms of a discipline or subdiscipline, the Laboratory, and/or the FBI;
   4. Demonstrate understanding of the relevance and reliability of a discipline and/or subdiscipline and the meaning and limitations of its related conclusions;
   5. Articulate the significance of the quality system.

B. Forensic examiner trainees are required to successfully complete at least one formal moot court exercise covering all discipline(s) and/or subdiscipline(s) recorded on their training plan. This can either occur in a single, comprehensive moot court exercise, or in multiple, individual discipline and/or subdiscipline moot court exercises. [A2LA R318 6.1 FI1.3], [ANAB AR 3125 6.2.2.2.d]
   1. The formal moot court exercise(s) must include licensed attorneys in all three roles (i.e., judge, prosecutor, and defense)
   2. The scheduling of the moot court exercise(s) will be coordinated by the TPM, the Forensic Examiner Training Program Manager (FETPM), and the Forensic Science Law Unit.
   3. The forensic examiner trainee will be responsible for preparing and distributing discovery packets to the participants (e.g., evaluators, attorneys) in the moot court exercise(s) in accordance with the timeframe requested by the participants.

C. FBI Laboratory personnel who are not expected to provide expert testimony as part of their job tasks are not required to complete a moot court exercise.

D. For each moot court exercise,
   1. A summary of expectations that contains details such as objectives, topics covered, and the evaluation method will be provided to the trainee and evaluators in advance.
   2. Evaluation requirements:
      i. Three evaluators are required for each moot court exercise using the rubric evaluation method as described in section 6.3. The *General*

Rubric Structures Form must be used. Two evaluators must be subject matter experts in the applicable discipline or subdiscipline and one evaluator will be from another discipline or subdiscipline and preferably from another FBI Laboratory unit. All evaluators must have testimony experience.

ii. The moot court evaluation method will be listed on the summary of expectations and followed in accordance with section 6.3.

iii. Moot court exercises will be video recorded and retained in the person's training records.

iv. The unit, discipline, and/or subdiscipline TPM will ensure that the evaluation method is reviewed with the trainee and the participants, as appropriate, prior to the moot court exercise.

E. There will be at least one practice session opportunity afforded to each trainee that includes performance feedback based on the designated rubric evaluation method for the moot court exercise.

F. If the trainee fails to successfully complete a moot court exercise, the Quality Manager will be notified in writing and a remediation plan will be developed for the trainee. A second attempt at the same exercise will be conducted after the conclusion of the remediation plan action steps.

G. Records for moot court exercises will be maintained in a person's training records. [A2LA R318 6.1 FI1.3]

6.3 Evaluation for FBI Laboratory Personnel

A. FBI Laboratory evaluation methods will be used to assess a person's knowledge, skills, and abilities for training topics identified in their training plan.

B. Trainees will be evaluated using one of the following three methods, as appropriate for each training topic listed on the training plan requiring evaluation:

1. Completion of task [Complete/Incomplete]
2. Determination of Accuracy [% passing threshold]
3. Rubric with a scale for evaluating performance levels that includes the thresholds of Non-Performance, Needs Improvement, Satisfactory, and Distinguished

6.3.1 Evaluation Method Development

A. Training topics that only need to be assessed as completed will use the *Completion of Task* method of recording 'complete/incomplete' in the person's training records.

B. Training topics that require an assessment of meeting a percentage threshold will use the *Determination of Accuracy* method. Unit, discipline and/or subdiscipline training manuals will define the score for a passing threshold. Scores will be recorded in each person's training records.

C. Training topics that require an assessment of multiple evaluation elements and determination of a performance level will use the *Rubric Evaluation* method. Each

rubric will follow the content and format detailed in the *General Rubric Structures Form*.

1. FBI Laboratory-required evaluation elements will be outlined within the *General Rubric Structures Form*.
2. Units, disciplines and/or subdisciplines may include additional evaluation elements. Those elements must follow the format and content designated in *General Rubric Structures Form*, as applicable.
3. Performance levels will be distinguished by using the terminology as follows:
    i. Non-Performance - "minimally..."
    ii. Needs Improvement - "partially..."
    iii. Satisfactory - "sufficiently..."
    iv. Distinguished - "extensively..."
4. A trainee and the trainee's supervisor will acknowledge in writing any written evaluations that rate at Non-Performance or Needs Improvement level.

6.3.2 Evaluation of Trainees

A. Individuals in a training program must successfully complete all applicable training requirements as listed in their training plan in order to be qualified to perform specific work for the FBI Laboratory.
B. Evaluation of trainee progress will be recorded on the *Trainee Evaluation Form (7-270)*. Trainee evaluation records will be maintained in a person's training records.
C. For Laboratory-required training topics, the trainee must meet the successful completion requirements of a training course or achieve the performance level of "Satisfactory" or "Distinguished" for required graded exercises.
D. For unit, discipline and/or subdiscipline training topics, the criteria of acceptable performance will be detailed in the applicable training manual.
E. A trainee will be removed from training under any of the following conditions when required as part of their training plan:
    1. Failure of two attempts to meet the successful completion requirements for Laboratory training courses (i.e., Common Core, Legal, Ethics).
    2. Failure of two of the same Laboratory-required communication training milestone exercises per category (i.e., public speaking, critical thinking, moot court).
    3. Failure of two of the same competency tests.
    4. Failure to successfully complete real/simulated laboratory activities as defined in unit, discipline and/or subdiscipline training manual.

6.3.3 Remediation

If a trainee does not meet the criteria for acceptable performance after the first attempt of an FBI Laboratory-required training course, communication milestone (when applicable), or competency test (when applicable); a remediation plan will be developed to address identified areas needing improvement. Additional causes for the development of a remediation plan will

be defined in a unit, discipline and/or subdiscipline training manual. All remediation plans will be recorded in a person's training records. [ANAB AR 3125 6.2.2.2.e]

6.3.4 Evaluation of Training Programs

The effectiveness of training will be evaluated via quarterly training program assessments coordinated by the FETPM. The FETPM will ensure the assessments are provided to Unit Chiefs and TPMs. The FETPM will when appropriate, assist TPMs with implementing changes to the applicable training program.

6.4 Qualification and Authorization for FBI Laboratory Personnel

A. If a person will be performing any of the following laboratory tasks, they must be authorized: [ISO 17020 6.1.5], [ISO 17025 6.2.5.e]
    1. Testing, all aspects including, as applicable, the use of equipment; [ISO 17025 6.2.6], [ANAB AR 3125 6.2.6 Note]
    2. Development, modification, verification, and validation of methods and procedures; [ISO 17025 6.2.6.a]
    3. Analysis of results; [ISO 17025 6.2.6.b]
    4. Review and authorization of results; [ISO 17025 6.2.6.c]
    5. Verification of results;
    6. Performing technical reviews;
    7. Expressing opinions or interpretations; [ISO 17025 7.8.7.1]
    8. Reporting results; [ISO 17025 6.2.6.c]
    9. Issuing *Laboratory Reports* and/or i3 products; and [ISO 17025 6.2.6.c]
    10. Evaluation of testimony.
B. Authorization is also required for personnel who handle evidence (e.g., evidence management personnel, forensic photographers) as well as those who maintain the quality system. [ISO 17020 6.1.5], [ISO 17025 6.2.5.e]
C. Qualification and authorization records for FBI Laboratory personnel will be generated and serialized as an EC in Sentinel using the *Template for Qualification & Authorization ECs* located in Sentinel. The FETPM, applicable Unit Chief, and Technical Leader (or supervisor if the trainee is not in a discipline or subdiscipline) are required approvers. [ISO 17020 6.1.10], [ISO 17025 6.2.5.e]

6.5 Supervising and Monitoring Competence

A. FBI Laboratory personnel are supervised according to the organizational charts and in accordance with FBI policy. [ISO 17025 6.2.5.d]
B. Continued monitoring of competence of personnel who perform laboratory activities and/or handle evidence will be conducted as described in Monitoring. [ISO 17020 6.1.5], [ISO 17025 6.2.5.f]

6.6 Continuing Education for FBI Laboratory Personnel

A. FBI Laboratory personnel will complete a minimum of eight hours of continuing education each fiscal year. Management and/or each unit will establish objectives

for the continuing education of personnel to meet the present and anticipated needs of the FBI Laboratory. [ISO 17020 6.1.6.c], [ANAB AR 3125 6.2.2.2.f]

B. Continuing education will be recorded on a person's FBI Virtual Academy transcript. [A2LA R318 6.1 FI1.7]

7 MEASUREMENT UNCERTAINTY EVALUATION

A. Units, disciplines, and/or subdisciplines will identify the contributions to measurement uncertainty. These contributions are recorded in each appropriate technical procedure, or the appropriate technical procedure will reference the location of the record(s) of the identified contributions if the record(s) is retained elsewhere. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, will be considered using the appropriate methods of analysis. [ISO 17025 7.6.1]

B. Technical procedures, when applicable, will include considerations for estimating the measurement uncertainty. The method of analysis for evaluation of measurement uncertainty: [ANAB AR 3125 7.6.1.1]
    1. Requires the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method; [ANAB AR 3125 7.6.1.1.a]
    2. Includes the process of rounding the expanded uncertainty; [ANAB AR 3125 7.6.1.1.b]
    3. Requires the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and [ANAB AR 3125 7.6.1.1.c]
    4. Specifies the schedule to review and/or recalculate the measurement uncertainty. [ANAB AR 3125 7.6.1.1.d]

C. Estimation of measurement uncertainty is based on an understanding of the theoretical principles or practical experience of the performance of the method. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation is made based on an understanding of the theoretical principles or practical experience of the performance of the method. [ISO 17025 7.6.3]
    1. Units, disciplines, and/or subdisciplines will evaluate or estimate measurement uncertainty when applicable, for all reported quantitative results. [ANAB AR 3125 7.6.3.1]

D. Unit, disciplines and/or subdisciplines will maintain the following records for each evaluation and estimation of measurement uncertainty: [ANAB AR 3125 7.6.4]
    1. Statement defining the measurand; [ANAB AR 3125 7.6.4.a]
    2. Statement of how traceability is established for the measurement; [ANAB AR 3125 7.6.4.b]
    3. The equipment (e.g., measuring device(s) or instrument[s]) used; [ANAB AR 3125 7.6.4.c]
    4. All uncertainty components considered; [ANAB AR 3125 7.6.4.d]
    5. All uncertainty components of significance and how they were evaluated; [ANAB AR 3125 7.6.4.e]

6. Data used to estimate repeatability, intermediate precision, and/or reproducibility; [ANAB AR 3125 7.6.4.f]
7. All calculations performed; and [ANAB AR 3125 7.6.4.g]
8. The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty. [ANAB AR 3125 7.6.4.h]

8 SELECTION, VERIFICATION, AND VALIDATION OF METHODS

A. The FBI Laboratory uses appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. The FBI Laboratory also uses appropriate methods and procedures for all associated data analysis and interpretation. [ISO 17025 7.2.1.1], [ANAB AR 3125 7.2.1.1.1]

B. If a technical procedure involves the comparison of an unknown to a known, the procedure requires the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s). [ANAB AR 3125 7.2.1.1.2]
    1. This requirement is not focused on the process of assessing an unknown in order to identify the test item that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known prior to the assessment of the unknown.

c. FBI Laboratory personnel select appropriate methods and procedures to meet the needs of the customer while considering the nature of the evidence, the request for examination, and any pertinent case information received. The methods are published either in international, regional or national standards; by reputable technical organizations; in relevant scientific texts or journals; as specified by the manufacturer of the equipment; or are developed or modified by the FBI Laboratory. [ISO 17020 7.1.1], [ISO 17025 7.1.1.d, 7.2.1.4]

D. FBI Laboratory personnel verify that they can properly perform methods before introducing them by ensuring they can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary. [ISO 17025 7.2.1.5], [A2LA R318 7.1 FI1.3]

8.1 Method Development

A. Method development involves the acquisition and evaluation of test data for the determination and optimization of conditions of a method to achieve consistent results. A method development plan will be prepared prior to developing a new method. [ISO 17025 7.2.1.6]

B. The method development plan will be reviewed and approved by the applicable Technical Leader. As method development proceeds, periodic review is carried out to confirm the needs of the customer(s) are still being fulfilled. Any modifications to the development plan are reviewed and authorized by the Technical Leader. If the

Technical Leader is the preparer, a SME will approve the plan/changes to the plan. [ISO 17025 7.2.1.6]

8.2 Method Validation

A. Method validation is the process of determining whether pre-defined performance requirements are met to declare the method fit-for-purpose. Standard methods, non-standard methods, and FBI Laboratory-developed methods must be validated prior to use in the FBI Laboratory. [ISO 17020 7.1.3], [A2LA R318 7.1 FI1.4], [ISO 17025 7.2.1.5, 7.2.2.1]
    1. If a significant modification (determined by applicable Technical Leader) needs to be made to an existing method/previously validated procedure, the influence of such changes will be evaluated. Where the changes are determined to affect the original validation, a new validation will be performed. [ISO 17025 7.2.2.2]
    2. When a previously validated procedure will be used in a new facility, a simplified validation (i.e., verification/performance check) will be required to ensure technically sound results can be produced. [ISO 17025 7.2.1.5, 7.2.2.1]

B. A validation plan will be prepared prior to validating a method, when modifications to an existing method/previously validated procedure are expected to affect the original validation, and when a previously validated procedure will be used in a new facility. The validation plan will be reviewed and approved by the Technical Leader. If the Technical Leader is the preparer, a SME will approve the plan.
    1. In developing the validation plan, the performance characteristics, as assessed for the intended use, will take into consideration the customers' needs and be consistent with specified requirements. [ISO 17025 7.2.2.3]

C. Validations will:
    1. Be as extensive as is necessary to meet the needs of the given application or field of application. [ISO 17025 7.2.2.1]
    2. Include the associated data analysis and interpretation steps. [ANAB AR 3125 7.2.2.1.1.a]
    3. Establish the data required to report a result, opinion, or interpretation. [ANAB AR 3125 7.2.2.1.1.b]
    4. Identify limitations of the method, reported results, opinions, and interpretations. [ANAB AR 3125 7.2.2.1.1.c]
    5. Include the conditions under which reliable results can be obtained.
    6. Include the use of known samples.

D. Appropriate Level 2 documents will define and/or reference the minimum requirements for a validation study within in a unit, discipline, and/or subdiscipline.

E. Units, disciplines, and/or subdisciplines will maintain records for a validation including:
    1. The validation procedure used; [ISO 17025 7.2.2.4.a]
    2. Specification of the requirements; [ISO 17025 7.2.2.4.b]

3. determination of the performance characteristics of the method; [ISO 17025 7.2.2.4.c]
4. The results obtained; [ISO 17025 7.2.2.4.d]
5. Statement on the validity of the method, detailing its fitness for intended use. [ISO 17025 7.2.2.4.e]

8.3 Software Acceptance/Validation

A. Software validation is the process of establishing that performance requirements are met to declare the software fit-for-purpose and function appropriately in the laboratory environment. Software applications that are not part of the testing process (e.g., Microsoft Office Suite) do not fall under this section.
B. New software or new modules of existing software to include commercial software and those developed by the FBI Laboratory will be validated. [ISO 17020 6.2.13.a], [ANAB AR 3125 7.11.2.1]
    - Note: Data generated through user acceptance testing of software may be used as part of a validation if it fulfills the requirements of a validation plan.
C. A software validation plan will be developed and will be approved by the appropriate subject matter expert. The version of the software validated will be tracked.
D. User acceptance testing (UAT) will be performed to verify that the application performs as expected prior to use.

8.4 Validation Summaries

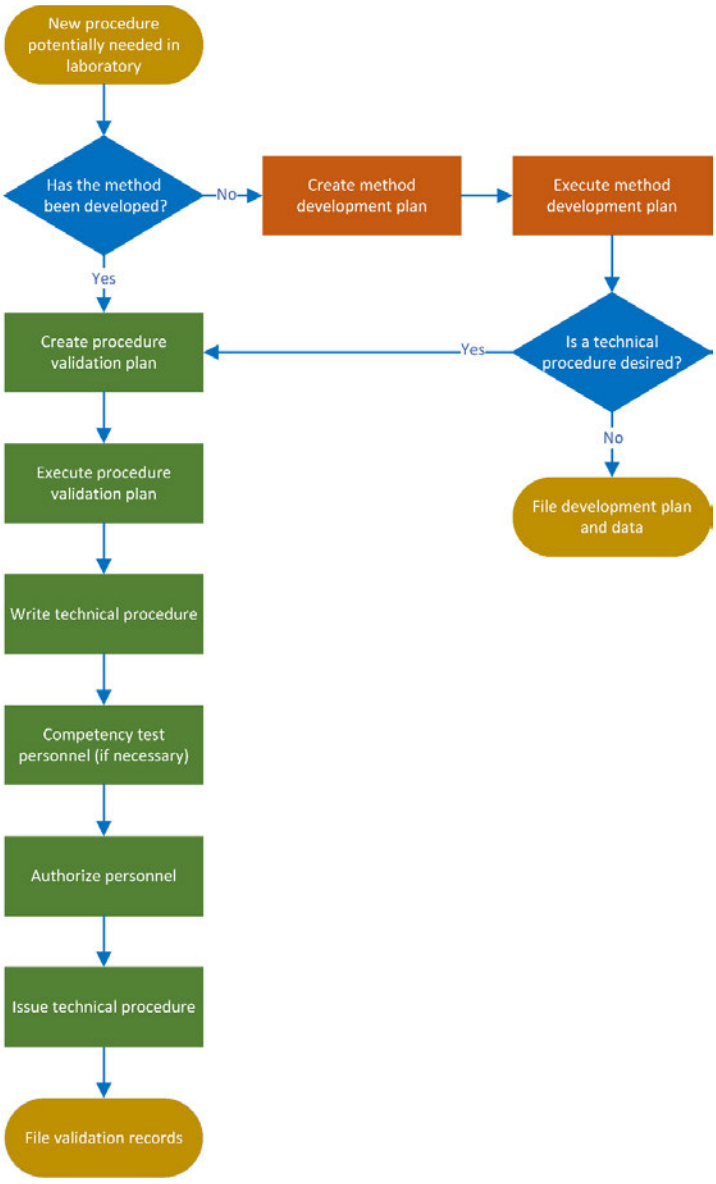
Validation summaries will be prepared for public posting with the associated technical procedure. [MEMORANDUM FOR HEADS OF DEPARTMENT COMPONENTS (justice.gov)]]

8.5 Competency Tests for New Procedures

A. Competency tests will be administered to each examiner and/or analyst who will apply a new procedure to laboratory activities (see section 6.1).
B. The Unit Chief and the Technical Leader may approve a validation to serve as demonstration of competency for personnel involved in that validation.

8.6 Records

Records of method selection, development, validation, to include software validations, and competency tests will be retained by the applicable unit, discipline and/or subdiscipline. [ISO 17025 7.2.1.5], [ANAB AR 3125 7.11.2.1], [A2LA R318 7.1 FI1.4]



Method Validation Flowchart

9 EQUIPMENT CALIBRATION/MAINTENANCE

9.1 Equipment

A. The FBI Laboratory is furnished with, or has access to, equipment needed for the correct performance of laboratory activities and that can influence the results. [ISO 17020 6.2.1, 6.2.2], [ISO 17025 6.4.1]

B. Equipment may include measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus as well as any other applicable equipment defined in Level 2 documents. [ISO 17025 6.4.1]

9.1.1 Equipment Identified in Resource Manager

A. Each piece of equipment entered in Resource Manager will receive a unique identifier and label that will, when practicable, be placed on the equipment. The Resource Manager fields will be populated. [ISO 17020 6.2.4, 6.2.15], [ISO 17025 6.4.13.a, b, d]
B. Equipment used for laboratory activities that requires calibration will be identified in Resource Manager or STACS, as appropriate. [ISO 17020 6.2.4, 6.2.15], [ISO 17025 6.4.13]

9.1.2 Equipment Outside of Permanent Control

When units, disciplines, and/or subdisciplines use equipment outside of their permanent control, they will ensure that the applicable requirements are met. [ISO 17025 6.4.2]

9.1.3 Equipment Handling, Transport, Storage and Use

Units, disciplines, and/or subdisciplines have Level 2 procedures for handling, transport, storage, and use of equipment to ensure proper functioning, and to prevent contamination or deterioration. [ISO 17020 6.2.5], [ISO 17025 6.4.3]

9.1.4 Reference Collections

Units, disciplines, and/or subdisciplines utilizing reference collections for identification, comparison, or interpretation purposes have each entry in the collection documented, uniquely identified, and handled properly to protect the characteristic(s) of interest. [ANAB AR 3125 6.4.3.2]

9.1.5 Reagents

A. Units, disciplines, and/or subdisciplines have procedures for checking the reliability of reagents. [ISO 17025 6.4.3], [ANAB AR 3125 6.4.3.1], [A2LA R318 6.2 FI1.2]
B. Reagents prepared in the FBI Laboratory are labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. [ISO 17025 6.4.3], [ANAB AR 3125 6.4.3.1]
C. Records are maintained by the units, disciplines, and/or subdisciplines. Units, disciplines, and/or subdisciplines identify who made the reagents and the components used in preparation. [A2LA R318 6.2 FI1.3, 6.2 FI1.4], [ISO 17025 6.4.3], [ANAB AR 3125 6.4.3.1]

9.1.6 Refrigerators and Freezers

Refrigerators and freezers that store evidence and/or items that have a direct effect on the validity of laboratory activities have their temperatures monitored and maintained as needed. [ISO 17020 6.2.11.c], [ISO 17025 6.4.1]

9.1.7 Software and Firmware

Software and firmware version records will be maintained by units, disciplines, and/or subdisciplines. [ISO 17025 6.4.13.a]

9.1.8 Equipment Placed or Returned into Service

Equipment used for laboratory activities must meet the requirements of the relevant technical procedure or applicable specifications. Before being placed into or returned to service, equipment that has a direct effect on the quality of laboratory activities is calibrated and/or performance checked by the applicable unit, discipline, and/or subdiscipline to verify it meets the specifications. Records will be maintained. [ISO 17020 6.2.6], [ISO 17025 6.4.4, 6.4.13.c]

9.1.9 Equipment Measurement Accuracy and/or Measurement Uncertainty

Units, disciplines, and/or subdisciplines ensure the equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. [ISO 17025 6.4.5]

9.1.10 Equipment Overloading/Mishandling/Power Interruption

A. Any equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements will be taken out of service. [ISO 17020 6.2.14], [ISO 17025 6.4.9]
    1. The equipment will be isolated to prevent use and/or clearly labeled or marked as being out of service until it has been returned into service. [Iso 17020 6.2.14], [ISO 17025 6.4.9]
B. Units, disciplines, and/or subdisciplines will determine and record the effect of the defect or departure from specified requirements and implement nonconforming work procedures. [ISO 17020 6.2.14], [ISO 17025 6.4.9]
C. If an instrument can be affected by a power interruption, units, disciplines, and/or subdisciplines will check the instrument operation after a shutdown, whether deliberate or otherwise.

9.1.11 Equipment Unintended Adjustments

Units, disciplines, and/or subdisciplines will take practicable measures to prevent unintended adjustments of equipment from invalidating test results. [ISO 17025 6.4.12]

9.1.12 Equipment Performance Checks

A. When performance checks are necessary to maintain confidence in the performance of equipment, units, disciplines, and/or subdisciplines will carry out these checks according to Level 2 procedures. [ISO 17020 6.2.9], [ISO 17025 6.4.10]
    1. Performance check procedures will be included in the appropriate technical procedure in which the equipment is used, in a stand-alone maintenance document, or in manufacturer-supplied procedures for maintenance. These

procedures will reflect current performance requirements based on the use of the equipment and will be readily available to appropriate personnel.

B. Performance check records will be maintained. If a bound notebook is used to capture the performance check records, only the cover or first page of the notebook must be labeled with the equipment's unique identifier. Performance check records may also be maintained in case notes. These records will include, at a minimum: [ISO 17025 6.4.13]
    1. Type or name of equipment. [ISO 17025 6.4.13.a]
    2. Equipment serial number or another unique identifier. [ISO 17025 6.4.13.b]
    3. Date of the performance check.
    4. Results of the performance check. [ISO 17025 6.4.13.c]
    5. Material used for the performance check, including unique identifying information, if applicable.
    6. Acceptance criteria, if applicable. [ISO 17025 6.4.13.f]
    7. Identity of person performing the performance check.

9.2 Traceability

A. Units, disciplines, and/or subdisciplines will establish and maintain metrological traceability of their applicable measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. [ISO 17020 6.2.7], [ISO 17025 6.5.1]

B. Units, disciplines, and/or subdisciplines will ensure measurement results are traceable to the International System of Units (SI) through: [ISO 17025 6.5.2]
    1. Calibration provided by a competent laboratory (See Calibration Service Providers) [ISO 17025 6.5.2.a]; or
    2. Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI [ISO 17020 6.2.10], [ISO 17025 6.5.2.b]; or
    3. Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards. [ISO 17025 6.5.2.c]

C. When metrological traceability of measurements to SI units is not technically possible, units, disciplines, and/or subdisciplines will demonstrate metrological traceability to an appropriate reference, for example: [ISO 17025 6.5.3]
    1. Certified values of certified reference materials provided by a competent producer; [ISO 17025 6.5.3.a]
    2. Results of reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison. [ISO 17025 6.5.3.b]

9.2.1 Alteration of Certified Reference Materials

If a certified reference material is changed in a way that alters the traceable measurement value (e.g., diluted), then the equipment used to alter the certified reference material (e.g.,

pipette, glassware) will be evaluated for applicability of measurement traceability accreditation requirements by the units, disciplines, and/or subdisciplines using that equipment. [ANAB AR 3125 6.5.1.4]

9.2.2 Calibration Service Providers

A. When measuring equipment and/or certified reference materials that are used to establish or maintain traceability are calibrated, the external supplier of the calibration service will be one of the following (if available): [ANAB AR 3125 6.5.1.1]
    1. A National Metrology Institute that is a signatory to the International Bureau of Weights and Measures (BIPM) International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA) with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB); or [ANAB AR 3125 6.5.1.1.a]
    2. A service supplier accredited to ISO 17025 by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) MRA, with the calibration of measuring equipment to be purchased listed in a scope of accreditation; or [ANAB AR 3125 6.5.1.1.b]
    3. An accredited reference material producer that is accredited to ISO/IEC 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC MRA, with a scope of accreditation covering the certified reference material to be purchased. [ANAB AR 3125 6.5.1.1.c]

B. In situations where a supplier that meets the above specifications is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased will be confirmed by the units, disciplines, and/or subdisciplines using that supplier. Objective evidence of the confirmation will be maintained by the units, disciplines, and/or subdisciplines. [ANAB AR 3125 6.5.1.2]

C. The FBI Laboratory does not perform calibrations or issue calibration certificates as part of its scope of accredited activities. [ISO 17025 7.6.2, 7.8.4, 7.8.4.1] [ANAB AR 3125 6.5.1.3, 7.2.1.1.3, 7.7.5.e, 7.8.1.2.3]

9.3 Calibration

A. Equipment that meets one or both of the following criteria will be calibrated. [ISO 17025 6.4.6]
    1. The measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
    2. Calibration of the equipment is required to establish the metrological traceability of the reported results.

B. Units, disciplines, and/or subdisciplines will ensure calibration was completed and ensure the calibration certificate provided by a vendor is reviewed for accuracy and

checked for conformance with applicable requirements for their needs. A record of this review will be maintained. [ISO 17025 6.4.13.e]

C. Unit, disciplines, and/or subdisciplines will ensure Resource Manager or STACS, as appropriate, is updated to record the calibration information in a timely manner. [ISO 17025 6.4.13.e]
D. Calibration records, including calibration certificates, for all equipment will be maintained by the unit coordinating the calibration. These records will be maintained on the UNET Equipment Calibration and Service site.
E. Equipment that requires calibration will not be used for laboratory activities if satisfactory calibration cannot be achieved. If the calibration has expired, personnel will verify the calibration status is satisfactory prior to using the equipment. (See Equipment Performance Checks)

9.3.1 Calibration Program

A. Units, disciplines, and/or subdisciplines have a calibration program described in a Level 2 document, which they review and adjust as necessary in order to maintain confidence in the status of the calibration(s). [ISO 17020 6.2.6], [ISO 17025 6.4.7]
B. Each calibration program includes: [ANAB AR 3125 6.4.7.1.a, b, c, d]
    1. A list of the equipment requiring calibration;
    2. Specifications for the calibration service provider(s);
    3. Specified requirements for the calibration; and
    4. The interval of calibration.

9.3.2 Calibration Interval

A. Units, disciplines, and/or subdisciplines will ensure that equipment requiring calibration is calibrated within the required intervals as specified in Level 2 documents.
B. Manufacturers' operating guidelines should be consulted to determine the recommended calibration interval, if applicable. However, equipment used infrequently, such that recommendations by the manufacturer cannot be followed, will be calibrated, or have its calibration status verified prior to use. (See section 9.1.12)

9.3.3 Labeling

Equipment requiring calibration will be labeled, coded, or otherwise identified to allow the user of the equipment to readily identify the calibration status or period of validity. [ISO 17025 6.4.8]

9.3.4 Reference values or correction factors

When calibration and reference material data will include reference values or correction factors, units, disciplines, and/or subdisciplines will ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements. [ISO 17025 6.4.11]

9.3.5 Adjustment or repair

If an adjustment or repair is performed due to a calibration that does not meet specifications, pre- and post-adjustment/repair data is retained. [ANAB AR 3125 7.5.1.6]

9.4 Maintenance

A. Maintenance is performed on equipment in order to ensure reproducible and uninterrupted operation; maintenance may also be corrective. Maintenance performed on a regular, predetermined schedule is based on manufacturer's recommendations (as available and relevant), historical observations of issues, operating experience, and/or how often the equipment is used. The interval for any equipment requiring preventive maintenance will be specified in a Level 2 document. [ISO 17020 6.2.3]
B. Units, disciplines, and/or subdisciplines will have maintenance procedures, including planned maintenance, for equipment that has a direct effect on the quality of laboratory activities in order to ensure proper functioning, and to prevent contamination or deterioration. [ISO 17020 6.2.5], [ISO 17025 6.4.3]
C. Maintenance will be performed on equipment:
    1. According to a regular, predetermined schedule (e.g., microscope maintenance performed annually);
    2. Based on routine monitoring of performance;
    3. Following adjustment of common parameters (e.g., head pressure, solvent degas); and/or
    4. When a piece of equipment cannot be properly calibrated, fails a performance check, fails to meet the performance characteristics established for the procedure(s), or otherwise produces unacceptable results (i.e., corrective maintenance).
        i. Equipment will be isolated to prevent use and/or clearly labeled or marked as being out of service until it has been returned into service. [ISO 17025 6.4.9]
D. Maintenance records will include information on the maintenance performed, where relevant to the performance of the equipment, and provide details of any damage, malfunction, modification to, or repair of, the equipment. If a bound notebook is used to capture maintenance records, only the cover or first page of the notebook needs to be labeled with the equipment's unique identifier. These records will be maintained by the units, disciplines, and/or subdisciplines. [ISO 17020 6.2.15], ISO 17025 6.4.13.a, b, g, h]
E. Unit Chiefs will ensure maintenance records provided by a vendor are reviewed for accuracy and checked for conformance with applicable requirements. A record of this review will be maintained.

10 MONITORING

A. The FBI Laboratory monitors its performance, including the performance of personnel. [ISO 17025 7.7.2], [ANAB AR 3125 7.7.4]
B. Proficiency testing, other interlaboratory comparisons, intralaboratory comparisons, or observation-based performance monitoring and testimony evaluations are used for monitoring the performance of personnel who perform laboratory activities (i.e., testing, sampling) and/or handle evidence. Auditing, complaints, and the annual management review of the quality system are also types of monitoring in the FBI Laboratory to ensure the validity of results. [ISO 17025 7.7.2.a, b]

10.1 Validity of Results Monitoring

A. Units, disciplines, and/or subdisciplines define applicable quality control procedures for monitoring the validity of results in Level 2 documents. [ISO 17025 7.7.1], [A2LA R318 7.1 FI1.2]
B. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the review of the results. [ISO 17025 7.7.1]
C. Monitoring the validity of results is planned and reviewed and includes the following, where appropriate:
    1. use of reference materials or quality control materials; [ISO 17025 7.7.1.a]
    2. use of alternative instrumentation that has been calibrated to provide traceable results; [ISO 17025 7.7.1.b]
    3. performance check(s) of measuring and testing equipment; [ISO 17025 7.7.1.c, 7.7.1.e]
    4. use of check or working standards with control charts, where applicable; [ISO 17025 7.7.1.d]
    5. replication of tests using the same or different procedures; [ISO 17025 7.7.1.f]
    6. retesting of retained items; [ISO 17025 7.7.1.g]
    7. correlation of results for different characteristics of an item of evidence; [ISO 17025 7.7.1.h]
    8. review of reported results, technical records, and testimony (See Testimony Monitoring); [ISO 17025 7.7.1.i], [ANAB AR 3125 7.7.1.l]
    9. intralaboratory comparisons; [ISO 17025 7.7.1.j]
    10. testing of blind sample(s). [ISO 17025 7.7.1.k)]
D. Data from monitoring activities is analyzed, used to control and, if applicable, improve the FBI Laboratory's activities. [ISO 17025 7.7.3]
    1. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported. [ISO 17025 7.7.3]

10.2 Performance Monitoring

10.2.1 Performance Monitoring Plan

A. Each Unit Chief will ensure a performance monitoring plan is developed and maintained for their personnel who perform laboratory activities and/or handle evidence. [ANAB AR 3125 7.7.6.a]
B. For personnel performing laboratory activities, the plan must ensure inclusion of a representative sample of the components/parameters and equipment/technologies within each discipline listed on the scope of accreditation. [ANAB AR 3125 7.7.6.b]
C. For personnel handling evidence, the plan must ensure that all personnel are monitored once over an accreditation cycle.
D. The plan will be maintained to cover the current cycle of accreditation and ensure that there are always four years of performance monitoring planned.

10.2.2 Performance Monitoring Requirements

A. Results will not be known or readily available to the person being monitored. [ANAB AR 3125 7.7.5.a]
B. Each person must participate to the extent they would perform the procedures in testing, and all relevant quality documents including technical procedures will be followed to the extent possible. [ANAB AR 3125 7.7.5.b]
C. Criteria for determining successful completion will be established prior to the monitoring activity. [ANAB AR 3125 7.7.5.c]
    1. Participants will be aware of the expectations of the activity prior to beginning the monitoring activity. [ANAB AR 3125 7.7.5.c]
D. A mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity will be recorded as described in a level 2 document or the *Performance Monitoring Other Than Proficiency Testing* (7-290a-c) form. [ANAB AR 3125 7.7.5.d]
E. Personnel conducting the monitoring (e.g., reviewers, verifiers) must be subject matter experts in the task(s) being monitored. Personnel overseeing the monitoring process (e.g., administration) do not need to be subject matter experts. [ISO 17020 6.1.8]
F. The date assigned identifies the day on which the participant was assigned a proficiency test, intralaboratory comparison, intralaboratory comparison, or observation-based performance monitoring. This date identifies the calendar year for which the test will be credited.
G. Proficiency test, intralaboratory comparison, and interlaboratory comparison identifications or associations will be verified, when appropriate. All proficiency tests, intralaboratory comparisons, and interlaboratory comparisons will be technically reviewed using the same procedures used for casework and administratively reviewed.
    1. If a person who will verify, technically review, and/or administratively review a proficiency test, intralaboratory comparison, and interlaboratory

comparison is participating in the same test distribution, they will not conduct any verifications or reviews until their testing is complete.

10.2.3 Proficiency Testing

A. Each examiner and analyst must complete at least one proficiency test annually in which they routinely perform testing to cover each discipline appearing on the FBI Laboratory's ANAB Scope of Accreditation or each subdiscipline as defined by the FBI Laboratory. Proficiency test results submitted to the test provider will be approved for release to ANAB. [ANAB 3125 7.7.2.1.a, b, and 7.7.4]
B. Proficiency tests that have been taken historically will continue to be taken by applicable personnel (e.g., hair, fiber, handwriting, document examination, paint, tape). [ANAB AR 3125 7.7.7.a]
C. Where available and appropriate (i.e., if it is a test the FBI Laboratory would perform on a submitted item, it is an appropriate test) for the work conducted, units will use a proficiency test provider who is accredited to ISO/IEC 17043 that is a signatory to the Asia Pacific Accreditation Cooperation(APAC) MRA or Inter-American Accreditation Cooperation (IAAC) Multilateral Recognition Arrangement (MLA) and has the applicable test(s) on its scope of accreditation. [ANAB AR 3125 7.7.7.a]
D. Where proficiency tests are not available or appropriate for the work conducted in an accredited discipline, alternate means of assessing performance must be approved by the accrediting body. [ISO 17025 7.7.2.b], [ANAB AR 3125 7.7.7.b]
E. Proficiency test results will be submitted to the proficiency test provider, if applicable, on or before the agreed upon due date. [ANAB AR 3125 7.7.7.c]
F. Proficiency test samples must be retained through the evaluation of a proficiency test and, when applicable, the resolution of any nonconformity(ies) associated with that proficiency test.

10.2.4 Other Performance Monitoring

A. If a proficiency test is not available or appropriate, an intralaboratory comparison, interlaboratory comparison, or observation-based performance monitoring is acceptable. [ANAB AR 3125 7.7.4]
B. Each examiner and analyst engaged in testing that does not appear on the FBI Laboratory ANAB Scope of Accreditation will successfully complete at least one interlaboratory or intralaboratory comparison per calendar year in their discipline. [ANAB AR 3125 7.7.4]
C. For personnel no longer participating in proficiency testing, other interlaboratory comparisons, or intralaboratory comparisons who are authorized to perform other laboratory tasks as described in the ANAB GD 3152, continued competence will be monitored each accreditation cycle by a review of continuing education of a technical nature, observation of a task, or by having another authorized person repeat a task. [ISO 17025 6.2.5.f]
D. When a person who performs laboratory activities is on extended leave; the Unit Chief and Technical Leader will ensure the person's continued competence is

monitored upon their return. This can occur through competency testing as described in section 6.1.3 and/or other means as described in a level 2 document. The length of leave considered to be "extended leave" will be at the discretion of the Technical Leader. However, any leave exceeding one half of an annual proficiency test cycle will be considered "extended leave." Once continued competence is monitored and recorded upon their return, the person can then resume independent casework or DNA databasing responsibilities.

10.2.5 *Nonconformities in Performance Monitoring*

A. Non-technical inconsistencies noted during the monitoring process will be recorded and addressed as appropriate.
B. Analytical/interpretive inconsistencies identified during the monitoring process will be recorded and the Technical Leader notified.
    1. The Technical Leader will determine if the inconsistency is an analytical/interpretive error.
    2. The Technical Leader will determine the steps needed to address the inconsistency and the final decision will be recorded.
    3. If the examiner involved in the inconsistency is the Technical Leader, a subject matter expert will determine if the inconsistency is an error and the steps needed to address the inconsistency. The final decision will be recorded.
    4. Analytical/interpretive errors identified during review of an external proficiency test can be corrected prior to submission to the provider.
C. Corrective Action
    1. If the steps needed to address the analytical/interpretive error result in the development of a CAP, the examiner and/or analyst will not conduct laboratory activities or report results until the appropriate corrective action steps have been completed and the examiner and/or analyst is authorized to resume conducting laboratory activities by the Unit Chief and Technical Leader. (See Nonconformities)
    2. The Unit Chief will ensure records of laboratory activities from the examiner and/or analyst are reviewed to ensure the activities have been conducted properly, the notes and results have been reviewed, and the appropriate conclusions have been rendered. This review will include all submissions that were completed since the last satisfactory performance monitoring activity in that discipline/subdiscipline and that are relevant to the error and/or the design of the performance monitoring activity.
    3. The examiner and/or analyst will complete remedial training and a requalification test in the discipline/subdiscipline in which the inconsistency occurred before being re-authorized to conduct laboratory activities.

10.2.6 Records of Performance Monitoring

A. The following records will be retained for all intralaboratory comparisons, interlaboratory comparisons, proficiency tests, and observation-based monitoring:
    1. Tasks that require evidence handling, and discipline(s) and/or subdiscipline(s) monitored [ANAB AR 3125 7.7.8.a]
    2. Design of the monitoring activity [ANAB AR 3125 7.7.8.b]
    3. Expected results [ANAB AR 3125 7.7.8.c]
    4. Location of FBI Laboratory where monitoring occurred [ANAB AR 3125 7.7.8.d]
    5. Records submitted to and received from a proficiency test provider, where applicable [ANAB AR 3125 7.7.8.e]
    6. Appropriate technical records [ANAB AR 3125 7.7.8.f]
    7. Evaluation of results and action taken for unexpected results [ANAB AR 3125 7.7.8.g]
    8. Feedback on individual performance provided to the participant. [ANAB AR 3125 7.7.8.h]
B. Records for continued monitoring of competence of personnel can be found in a unit's proficiency testing, other interlaboratory comparison, intralaboratory comparison records, observation-based records, evaluation of testimony records, and technical and administrative reviews of casework. [ISO 17020 6.1.10]
C. A record of the continued monitoring of competence of personnel no longer participating in proficiency testing, other interlaboratory comparisons, or intralaboratory comparisons who are authorized to perform other laboratory tasks as described in the ANAB GD 3152 is retained in the unit, discipline, and/or subdiscipline.

10.3 Customer Feedback

A. The FBI Laboratory receives customer feedback through multiple means. The customer may provide unsolicited feedback, or the laboratory may request feedback from the customer. [ISO 17025 8.6.2]
B. All feedback will be considered as part of the continual improvement of the FBI Laboratory. [ISO 17025 8.6.2]

10.3.1 Laboratory Initiated Request for Feedback

A. *Customer Satisfaction Assessments* (FD-1000) will be provided for *Laboratory Reports* for new submissions. A *Customer Satisfaction Assessment* will be attached to the *Laboratory Report*, or the customer will be directed to the location of an electronic *Customer Satisfaction Assessment* they can complete.
B. For i3 products and/or major cases, as determined by the Laboratory Director, the Unit Chief(s) will develop the appropriate frequency to assess customer satisfaction using the *Customer Satisfaction Assessment*.

C. A *Customer Satisfaction Assessment* received with a "No" or "Unsatisfactory" response will be considered a complaint and will be addressed as described in section 10.3.2.2.
D. Any other form used to solicit feedback from a customer that indicates dissatisfaction, or a low score will be considered a complaint and will be addressed as described in section 10.3.2.2.
E. FBI Laboratory personnel may also solicit feedback through direct communication with a customer.

10.3.2 Complaints

A. As part of the FBI Laboratory's commitment to provide reliable forensic examinations and services, personnel will take appropriate steps to address valid complaints regarding their services. [ISO 17020 7.5, 7.6], [ISO 17025 7.9.1]
B. A complaint is the expression of dissatisfaction relating to the activities or results of the FBI Laboratory by any organization or person (internal or external to the laboratory), where a response is expected from the laboratory.

10.3.2.1 Handling Complaints

A. FBI Laboratory management:
    1. Receives, evaluates, and makes decisions on complaints. [ISO 17020 7.5.1], [ISO 17025 7.9.1]
    2. Tracks, records, and investigates complaints, including actions undertaken to resolve them. [ISO 17020 7.6.1.b], [ISO 17025 7.9.3.b]
    3. Ensures any appropriate action is taken. [ISO 17020 7.6.1.c], [ISO 17025 7.9.3.c]
    4. Is responsible for all decisions at all levels of the process for handling complaints. [ISO 17020 7.5.4], [ISO 17025 7.9.2]
    5. Ensures the process for handling complaints is available to any interested party by posting this document on the publicly available website: https://fbilabqsd.fbi.gov. [ISO 17020 7.5.2], [ISO 17025 7.9.2]

10.3.2.2 Process to Receive, Evaluate, and Make Decisions on Complaints

A. Upon receipt of a complaint, the appropriate Unit Chief will be notified. Complaints may be received through feedback requests initiated by the FBI Laboratory (e.g., Customer Satisfaction Assessment), other interactions that occur during the examination of evidence, and through feedback initiated by customers.
    1. The Unit Chief will gather and verify all necessary information to confirm whether the complaint relates to laboratory activities that their unit is responsible for and, if so, investigate the complaint to determine the validity of the complaint, and what actions to take. [ISO 17020 7.5.3, 7.6.1.a, 7.6.2], [ISO 17025 7.9.1, 7.9.2, 7.9.3.a, 7.9.4]
B. If the Unit Chief determines the complaint is a nonconformity, it will be addressed as such. [ISO 17025 7.9.3.b]

C. The Unit Chief will notify other laboratory management of the complaint, when appropriate, or when the complaint relates to laboratory activities that another unit is responsible for.

10.3.2.3 Records, Progress and Outcome

A. Unit Chiefs will ensure records are maintained of all complaints, any relevant investigations, actions taken, and responses. [ISO 17020 7.6.1.b]
B. Unit Chiefs will acknowledge receipt of a complaint and provide progress reports and the outcome to the complainant. [ISO 17020 7.6.3], [ISO 17025 7.9.5]
C. The outcomes to be communicated to the complainant will be made by, or reviewed and approved by, personnel not involved in the original laboratory activities in question. [ISO 17020 7.6.4], [ISO 17025 7.9.6]
D. When practicable, the Unit Chief will give formal notice of the end of the complaint handling to the complainant (i.e., stating that this will be the final communication regarding the complaint). [ISO 17020 7.6.5], [ISO 17025 7.9.7]

10.4 Internal Quality Assurance Audits

10.4.1 Auditor Training

A. An auditor must successfully complete an approved course.
B. The Quality Manager will determine if a course will be approved.
C. The Audit Program Manager will maintain a list of approved courses.
D. The Audit Program Manager will also maintain a list of auditors that have completed an approved course.

10.4.2 Audit Planning

A. Internal audits will be conducted at least annually. [ISO 17020 8.6.4], [ISO 17025 8.8.1.a], [ANAB AR 3125 8.8.1.1]
B. The Audit Program Manager will prepare a schedule annually for the internal audits based on a risk evaluation of laboratory's quality system, including laboratory activities, changes in those activities, and the results of previous audits. [ISO 17020 8.6.2, 8.6.3], [ISO 17025 8.8.1.a, b, 8.8.2.a, b]
C. A summary of this risk evaluation will be recorded, approved by the Quality Manager and maintained. [ISO 17025 8.8.1.a]
D. The schedule will identify the topics and approximate dates of the audits. This schedule is a guide and may be changed at the discretion of the Quality Manager or Audit Program Manager. [ISO 17025 8.8.2.a]
E. Audit schedules/plans must include direct observation of a sampling of the laboratory activities within each discipline and subdiscipline, and evidence handling activities. [ANAB AR 3125 8.8.2.b.1]

10.4.3 Preparing for the Audit

A. The Audit Program Manager will identify an audit team leader(s) when appropriate, and ensure auditors are identified, as needed, to assist in performing an audit. If an audit team leader is identified, the audit team leader will coordinate the audit, as directed by the Audit Program Manager. [ISO 17025 8.8.2.a]
B. The Audit Program Manager and/or audit team leader will ensure the selected auditors are on the list of internal auditors. [ISO 17020 8.6.5.a], [ISO 17025 8.8.2.a]
C. The Audit Program Manager will ensure an audit checklist is prepared and accessible to the auditee(s) and the auditor(s). [ISO 17025 8.8.2.a, b]

10.4.4 Conducting the Audit

A. The auditor(s) will, as necessary, review records, interview personnel, and/or observe conditions and facilities to collect data on conformance with requirements and effectiveness of quality control measures. An auditor will not review their own work, when practicable. [ISO 17020 8.6.5.b], [ANAB AR 3125 8.8.1.a.1]
B. The audit checklist will be used to record the audit data and any pertinent questions, observations, and/or comments identified during the audit. [ISO 17025 8.8.2.e]
C. The audit notification will identify any nonconformities and recommendations. [ISO 17020 8.6.5.e], [ISO 17025 8.8.2.c, e]

10.4.5 Notification and Acknowledgement of the Audit Results

A. For any audit topics that are found to be compliant with all requirements or contain only recommendation(s), the applicable Quality Assurance Representative, Unit Chief, and Technical Leader(s) will be notified. [ISO 17020 8.6.5.c], [ISO 17025 8.8.2.c, e]
B. If an audit identifies a nonconformity(ies), the applicable Quality Assurance Representative, Unit Chief and Technical Leader(s) will be notified and will record acknowledgement of the nonconformity(ies). [ISO 17020 8.6.5.c, d], [ISO 17025 8.8.2.c, d, e]
    1. If the audit identifies the need for a *Corrective Action Plan*, the Quality Manager will review and acknowledge the audit results prior to notification of unit personnel. [ISO 17025 8.8.2.c, d, e]
    2. If the need for a *Corrective Action Plan* is identified during an audit of a FASU managed process, the Forensic Services Support Section Chief will acknowledge the audit results in place of the Quality Manager. [ISO 17025 8.8.2.c, d, e]
C. If any edits to the audit results are identified, the Audit Program Manager will be notified for resolution, and the approval process will restart.

10.4.6 Closure of Audits

A. The resolution status of all audit nonconformities will be monitored by the Audit Program Manager and will be accessible by each Quality Assurance Representative,

Unit Chief, Technical Leader, and Quality Manager and Audit Program Manager. [ISO 17020 8.6.5.d], [ISO 17025 8.8.2.c, d]

B. As nonconformities are addressed, the resolution status of each audit nonconformity will be updated to indicate closure. [ISO 17025 8.8.2.c, d]

10.4.7 Audit Records

A. The following records will be generated and/or retained by FASU: [ISO 17020 8.6.5.f], [ISO 17025 8.8.2.e]
   1. List of approved auditor courses.
   2. List of approved auditors.
   3. Annual audit schedule and associated risk evaluation summary.
   4. Completed audit checklists and/or a summary checklist, if applicable.
   5. Audit results and acknowledgements, as applicable.

10.5 Management Review

FBI Laboratory Executive Management and the Quality Manager evaluate the quality system to ensure its continued suitability, adequacy, and effectiveness, to include the quality requirements and objectives. The management review is conducted annually and is used as the foundation for future development of FBI Laboratory objectives as well as any necessary changes or improvements to the quality system. [ISO 17020 8.5.1.1, 8.5.1.2], [ISO 17025 8.9.1], [ANAB AR 3125 8.9.1.1]

10.5.1 Management Review Inputs

A. The inputs to management review are recorded and include information related to the following [17020 8.5.2], [ISO 17025 8.9.2]:
   1. Changes in internal and external issues relevant to the FBI Laboratory;
   2. Fulfillment of objectives;
   3. The suitability, adequacy, and completeness of quality system documents for meeting the quality objectives of the FBI Laboratory and ISO 17025 and ISO 17020 standards, as applicable;
   4. Status of actions from previous management reviews;
   5. Outcome of any recent internal audits;
   6. Corrective and preventive actions, including their status;
   7. External audits and/or assessments;
   8. Changes in the volume and type of work being performed or in the range of laboratory activities;
   9. Customer and personnel feedback;
   10. Complaints;
   11. Effectiveness of any implemented improvements;
   12. Adequacy of the organizational structure, personnel training, and resources to implement the FBI Laboratory quality system and fulfill its objectives;
   13. Results of risk identification;
   14. Outcomes of the assurance of the validity of results; and

15. Other relevant factors, such as monitoring activities and training.

10.5.2 Records of Management Reviews

A. Records of management reviews are serialized in Sentinel and include all decisions and actions related to: [ISO 17020 8.5.1.3, 8.5.3], [ISO 17025 8.9.3]
    1. The effectiveness of the quality system and its processes;
    2. Tmprovement of the laboratory activities related to the fulfillment of the accrediting bodies' requirements;
    3. Provision of required resources; and
    4. Any issues identified and actions taken to address them.

10.6 Testimony Related Activities

A. The requirements for testimony related activities apply to FBI Laboratory personnel who: [DOJ Testimony Monitoring Framework]
    1. Provide expert testimony as part of their current and past FBI Laboratory job duties (i.e., testifying personnel).
    2. Manage testifying personnel.
    3. Conduct testimony evaluations.
    4. Support testimony related activities.
B. Fact based testimony will be addressed by units or discipline/subdiscipline as needed.

10.6.1 Curriculum Vitae (CV)

A. Testifying personnel will:
    1. Maintain a CV electronically and keep it up to date.
    2. Review their CV for accuracy prior to providing it to agents, court officials, and the Forensic Science Law Unit (FSLU) of the Office of General Counsel (OGC).
B. The CV will:
    1. Not contain any official seal.
    2. Include a listing of testimonies for the previous four years, including depositions and grand jury testimonies (unless prohibited).
    3. Not contain references to testimonies older than four years.
    4. Include the case name (e.g., United States v. John Doe), the year of the testimony, the jurisdiction (e.g., Eastern District of New York) or location (i.e., city and state), and the subject matter of the testimony (e.g., discipline).

10.6.2 Testimony Requests

A. Testifying personnel will notify their management of any request for their testimony.
B. Upon receipt of a subpoena request to testify, personnel will notify OGC.
C. Testifying personnel will ensure the subpoena is attached to the associated entry in the testimony tracker.

1. If the request for testimony is received in a manner other than a subpoena (e.g., verbal request, email request), testifying personnel will request a subpoena and notify OGC.

D. FBI Laboratory personnel will notify the DTMPM if they are made aware of a request for testimony or testimony provided by former FBI Laboratory personnel.
E. If the DTMPM is notified of testimony by former FBI Laboratory personnel, the requirements in this section will be followed if practicable.
F. FBI Laboratory personnel, who are no longer working in the same position/discipline which the testimony will occur, will discuss their anticipated testimony with the appropriate Technical Leader and notify OGC.
    1. The witness will review the relevant Approved Standards for Scientific Testimony and Report Language (ASSTR) and Uniform Language for Testimony and Reports (ULTR) prior to their testimony, when applicable.
    2. All associated meetings and reviews will be recorded as a comment on the appropriate entry in the testimony tracker.

10.6.3 Discovery Requests

A. Discovery Requests will be coordinated through FSLU.
B. Testifying personnel will:
    1. Ensure that all reports, 1A files, updated CV, major and minor deviations associated with the case, and applicable Level 2 documents in use at the time of their examinations are provided in discovery.
    2. Ensure the appropriate Level 2 documents are added to the appropriate folder on the Discovery Request SharePoint site.
    3. Include a request for prior transcripts as part of the same request on the Discovery Request SharePoint site if the discovery request includes a request for prior transcripts.
C. Upon receipt of all material associated with the discovery request (e.g., Level 2 documents, transcripts request, CV, 1A), the DTMPM will ensure:
    1. Laboratory Quality System documents (applicable level 1 and 2 documents) are provided to FSLU.
    2. Supporting records submitted are in accordance with the request.
    3. Any available requested transcripts for the testifying personnel are provided.
D. Discovery request entries will be retained permanently in the Discovery Request SharePoint site.

10.6.4 Giglio Requirements

A. The FBI Laboratory and its employees must disclose to a prosecutor all potential Giglio information as early as possible prior to providing a sworn statement or testimony in any criminal investigation or case.
B. Giglio information includes all information that could potentially be used by the defense to impeach a witness. This includes information that could be used by the defense to call into question the accuracy and/or strength of an examiner's

professional conclusion. This also encompasses personal choices and circumstances which occur outside the context of a criminal investigation and could potentially be used by the defense to attack a witness' credibility or character for truthfulness, or information that could potentially be used to suggest a witness is biased in favor of the prosecution or against a defendant. However, potential impeachment material may be found in a myriad of forms and is not limited to these.

C. Upon receipt of a Giglio request, the FBI Laboratory will disclose all agency-held information that could potentially be used for impeachment purposes, including:
    1. Errors made during proficiency tests.
    2. Allegations or findings of unsatisfactory and/or inaccurate casework performance.
    3. Testimony in violation of the ULTRs or ASSTRs (substantive violation). (See Substantive Violations and Materially Inaccurate Statements)
    4. Testimony that does not violate the ULTRs or ASSTRs but contains a material inaccuracy. (See Substantive Violations and Materially Inaccurate Statements)
    5. Information required to be disclosed as a result of the 1997 Department of Justice Office of the Inspector General Report or Microscopic Hair Review.
    6. Personnel records reflecting allegations or findings of misconduct that reflect on the candor or possible bias of an employee.
    7. Any additional information that may reasonably be used for impeachment purposes.
D. A testimonial presentation that has been found to contain a substantive violation, or that is found (as determined by OGC or the sponsoring prosecutor, or by a court ruling) to contain a material inaccuracy, or that has been deemed by OGC to merit a formal disclosure due to the potential for it to be considered materially inaccurate is considered potential Giglio material and will be disclosed during the established discovery process.
E. Disclosures of potential Giglio information held by the agency will be coordinated through OGC.
F. Upon notification that a Giglio request has been received, the notified employee must also contact the prosecutor to schedule a candid conversation to disclose any information they believe could potentially constitute Giglio (impeachment) information.

10.6.5 Requirements When Providing Testimony

A. All personnel providing expert testimony must provide testimony such that:
    1. Testimony is consistent with FBI Laboratory procedures regarding testimony about the forensic analysis and any associated interpretations.
    2. Testimonial opinions, conclusions, and statements regarding case-specific facts or data are properly qualified and do not exceed the limitations of any relevant method or discipline. [ISO 17025 7.8.7.1]
    3. Conclusions are in conformity with the applicable ASSTR document(s), which are in accordance with the applicable Department of Justice approved ULTR.

10.6.6 Tracking Testimony Details

All FBI Laboratory testifying personnel will ensure their testimony is entered into the testimony tracker and all applicable fields completed with the appropriate information including the date of their most recent testimony or refresher exercise or if a person has not testified, the date of their authorization/qualification.

10.6.7 Testimony Monitoring

The expert testimony of FBI Laboratory personnel will be monitored through direct observation or through transcript review. [ISO 17025 6.2.5.f], [ANAB AR 3125 7.7.1.l.4, 5, 6, 7, 8], [A2LA R318 6.1 FI1.5, FI1.6]

10.6.7.1 Authorized Evaluators

A. FBI Laboratory personnel will not conduct a testimony evaluation of their own testimony. [ANAB AR 3125 7.7.1.l.2]
B. Technical Leaders are authorized to conduct testimony evaluations in their discipline/subdiscipline.
C. A Technical Leader and the appropriate Unit Chief may authorize additional personnel to conduct testimony evaluations.
    1. Authorized personnel must have been previously competency tested in the discipline/subdiscipline they are evaluating. [ANAB AR 3125 7.7.1.l.1]
    2. This authorization will be recorded in Sentinel.

10.6.8 Transcript Requests

A. A transcript will be requested for every expert testimony provided and evaluated when received.
B. The DTMPM will ensure a transcript is requested for each expert testimony logged in the testimony tracker. The initial transcript request, follow up requests, communications regarding the request, and transcript receipt date will be recorded in the testimony tracker.
C. If a transcript is received by anyone other than the DTMPM, the person will notify the DTMPM of the date of the receipt of the transcript, and the transcript will be forwarded to the DTMPM for retention either upon receipt or after reviews are complete.

10.6.9 Transcript Review and Evaluation

A. All transcripts received will be reviewed and evaluated using the *Evaluation of Testimony* (7-256). [ISO 17025 7.7.1.l.5]
B. The *Evaluation of Testimony* and any associated notifications will be retained by the witness' unit or applicable support unit.
C. Video and audio recordings, if the voices are readily distinguishable, will be treated as transcripts.

D. All testimony reviews, evaluations and the related meetings, if applicable, must be completed within 30 calendar days of the receipt of the transcript in the FBI Laboratory or the direct observation of the testimony.
E. Extensions of the review period with cause (e.g., parental leave, extended deployment) may be approved by the appropriate Unit Chief or Technical Leader with a written notification to the DTMPM.

10.6.10 Witness Review of Transcript

A. The expert witness will review the transcript of their testimony, and complete Section A of the *Evaluation of Testimony*. This review provides an opportunity for witness input prior to the evaluation. [ISO 17025 7.7.1.l.5]
B. The witness will ensure the date their review is completed is entered into the testimony tracker.
C. If a transcription error is detected that impacts the substance of the person's testimony, the witness will notify their manager and OGC and ensure that any written communication regarding such transcription errors will be entered into the associated case file(s)in Sentinel and provide a copy to the DTMPM.
D. This written communication will also be added as an addendum to the transcript retained by the DTMPM.

10.6.11 Testimony Evaluator Review of Transcript

A. The authorized testimony evaluator will review the transcript. [ISO 17025 7.7.1.l.5]
B. The evaluator will determine if there are any issues detected in the testimony. Issues can be one of three types: [ISO 17025 7.7.1.l.8]
    1. Substantive violation;
    2. One or more potential materially inaccurate statements were made; and/or
    3. Other feedback to be given to improve the witness' testimony.
C. After evaluating the transcript, the authorized testimony evaluator will complete Section B of the *Evaluation of Testimony*.
D. If a "Y" response is marked for any of the questions in Section B of the *Evaluation of Testimony*, the testimony is deemed to have a substantive violation and will be considered unsatisfactory. (See Substantive Violations and Materially Inaccurate Statements)
E. If "N" responses are marked for all the questions in Section B of the *Evaluation of Testimony*, the testimony is considered satisfactory.
F. A testimony can be deemed satisfactory (i.e., "N" responses for all questions in Section B) and still have recommendations for improvement which will be recorded on the *Evaluation of Testimony*.
G. If an evaluator feels there is a statement that potentially is materially inaccurate, they will reference the Addressing a Materially Inaccurate Statement in Testimony in section 10.6.14.4 for guidance.
H. Other concerns noted during the evaluation can be addressed via the Nonconformities section or in another manner suited to the issue.

I. The testimony evaluator will ensure the date their evaluation is completed is entered into the testimony tracker.

10.6.12 Notification to Witness of Completed Evaluation

A. The testimony evaluator will provide notification of completion of the *Evaluation of Testimony* and any feedback on the testimony to the witness and their manager.
B. The notification date will be recorded in Section C of the *Evaluation of Testimony* and in the testimony tracker.
C. The witness and the manager will acknowledge receipt of feedback.
D. If there are no concerns and no follow up is needed, the notification can be provided via email to the witness and manager. A record of the notification will be retained with the *Evaluation of Testimony*.
E. Testimony determined to have issues or to need follow up requires feedback to be provided in a meeting with the witness.
    1. The witness' manager must also attend this meeting if a testimony is deemed unsatisfactory or at the testimony evaluator's request
    2. The manager will check the appropriate box on the *Evaluation of Testimony* indicating their attendance.

10.6.13 Direct Observation, Review, and Evaluation

A. An authorized testimony evaluator may directly observe an expert witness testify as an option for testimony monitoring.
B. After testifying, the expert witness will complete Section A of the *Evaluation of Testimony*. This review provides an opportunity for witness input prior to or in conjunction with the evaluation.
C. The witness will ensure the date their review is completed is entered into the testimony tracker.
D. The testimony evaluator will complete Section B of the *Evaluation of Testimony*.
E. The testimony evaluator will ensure the date their evaluation is completed is entered into the testimony tracker.
F. A transcript of the testimony will still be requested and retained. Subsequent review and evaluation of the transcript upon receipt is not required.

10.6.14 Substantive Violations and Materially Inaccurate Statements

10.6.14.1 Substantive Violation in Testimony

A. The term substantive violation will be interpreted as a meaningful or significant violation of any requirement listed in section 10.6.5, within the context of the entirety of the expert witness' testimony.
B. A substantive violation is not a trivial misstatement or the inartful phrasing of a testimonial statement.
C. In addition, a misstatement that is later corrected during a testimonial presentation or that constitutes an isolated reference clarified by the balance of an expert

witness' testimony would not generally be considered a substantive violation of the listed criteria.

D. A statement made by counsel or the judge at a time when an expert witness is not afforded an opportunity to intercede, such as during opening or closing remarks, would not constitute a substantive violation.

10.6.14.2 Addressing a Substantive Violation in Testimony

A. If the evaluator identifies testimony that is potentially noncompliant with the criteria listed in section 10.6.5, the evaluator will consult with OGC and the sponsoring attorney to determine if a substantive violation has occurred. This consultation will be recorded in Section C of the Evaluation of Testimony.
B. The final determination of whether the testimony contained a substantive violation is made by the authorized testimony evaluator after obtaining input from OGC and the sponsoring attorney.
C. If the evaluator concludes the testimony contained a substantive violation (i.e., any "Y" responses in Section B of the *Evaluation of Testimony*), the testimony evaluator will notify the witness' manager in writing at the time this is determined.
D. The testimony evaluator will prepare a detailed explanation of the reason(s) for determining the testimony was unsatisfactory and recommendations for improvement.
E. The explanation and recommendations will be attached to the Evaluation of Testimony and signed and dated by the witness, the testimony evaluator, and the witness' manager.
F. Additionally, for substantive violations, a Corrective Action Plan will be initiated. (See Nonconformities) [A2LA R318 6.1 FI1.6]
G. The DTMPM will be notified of any testimony deemed unsatisfactory.
H. The DTMPM will track all testimonies deemed unsatisfactory and retain a copy of the completed Evaluation of Testimony form and written notification to the sponsoring attorney.
I. When practicable, the witness' next testimony will be directly observed.

10.6.14.3 Materially Inaccurate Statement in Testimony

A. Testimony may be compliant with the requirements section 10.6.5 (i.e., does not constitute a substantive violation), but still contain one or more materially inaccurate statements.
B. A materially inaccurate statement is one which tends to make any fact *at issue* before the court more or less likely.
C. A "materially inaccurate" statement may include one which impacts the strength of a person's conclusion.
    - Note: An example of a materially inaccurate statement may be found where a person provides different answers during direct and/or cross examination, if such differing answers bear on the same fact, which is at issue before the Court.)

10.6.14.4 Addressing a Materially Inaccurate Statement in Testimony

A. If an evaluator identifies a potential materially inaccurate statement, the evaluator will notify OGC to evaluate the materiality of the inaccurate statement(s) within the context of the court proceeding as a whole, and OGC will determine if formal disclosure of the statement to the sponsoring prosecutor is necessary.
B. A detailed explanation of the findings of the testimony evaluator, the discussion with OGC and other pertinent individuals, and the outcome of the deliberations will be retained with the *Evaluation of Testimony.*
C. The witness's manager will be notified of any such materially inaccurate statements or any other statements deemed by OGC to merit a formal disclosure due to the potential for it to be considered materially inaccurate.
D. Regardless of whether the testimony is determined to be materially inaccurate, for any nonconforming testimony that is not determined to be a substantive violation, the manager will ensure the Nonconformities section is followed. [A2LA R318 6.1 FI1.6]
E. The witness' manager will ensure the DTMPM is notified of any testimony that is found (as determined by OGC or the sponsoring prosecutor, or by a court ruling) to contain a material inaccuracy, or that has been deemed by OGC to merit a formal disclosure due to the potential for it to be considered materially inaccurate.
F. The DTMPM will track all such testimonies and retain a copy of the completed *Evaluation of Testimony* and written notification to the sponsoring attorney, as applicable.

10.6.15 Transcript Retention

A. Transcripts will be retained electronically by the DTMPM for at least four years from the date the testimony was provided.
B. Before deleting a transcript, the DTMPM will contact the appropriate Unit Chief to determine if a redacted copy will be retained for training purposes.
    1. The DTMPM will redact appropriate identifying information prior to providing the transcript to the unit.
    2. Video and audio recordings cannot be redacted and will not be retained for training purposes.
C. Transcripts that are found to have substantive violations, material inaccuracies, or for which disclosure was made by OGC as described in section 10.6.4 will be retained permanently by the DTMPM.
D. Discovery requests asking for prior transcripts where any such transcripts are retained will be reviewed with OGC to determine what will be provided.
E. Transcripts will not be retained by the FBI Laboratory in any manner other than those described above.

10.7 Refresher Testimony Exercises When a Person Has Not Testified

A. Testifying personnel who do not provide expert testimony at least once in a five-year time period will participate in a refresher testimony exercise. [A2LA R318 6.1 FI1.5]

B. The refresher testimony exercise will occur no more than 60 calendar days after the end of the five years (i.e., date of last moot court exercise, date of last refresher testimony exercise, date of last testimony). [A2LA R318 6.1 FI1.5]
C. Each Unit Chief who manages testifying personnel will ensure that the need for refresher testimony exercises (i.e., testifying personnel that do not testify at least once in five years) is monitored in their unit.
D. The person's Unit Chief and applicable Technical Leader will define the requirements of the refresher testimony exercise and provide them to the person in writing at least 30 days prior to the exercise.
E. The refresher testimony exercise will be viewed by the person's Unit Chief and the applicable Technical Leader.
F. The person's Unit Chief and applicable Technical Leader will provide feedback tothe person at the conclusion of the refresher testimony exercise.
G. Feedback may be provided verbally.
H. If the exercise is successfully completed, the Unit Chief will ensure the refresher testimony exercise is documented in the testimony tracker.
    1. A comment will be added to the corresponding Testimony Tracker record indicating who was present at the exercise.
    2. Any fields not applicable to the refresher testimony exercise will be marked as such in the testimony tracker.
    3. Results and other written records created during the exercise will be retained in the person's unit. [A2LA R318 6.1 FI1.6]
I. If the person's Unit Chief or applicable Technical Leader determine that the exercise was not successfully completed, the Unit Chief will ensure a *Corrective Action Plan* is initiated as described in the Nonconformities section. [A2LA R318 6.1 FI1.6]

11 RECORDS MANAGEMENT

Records are retained as stated throughout this document and according to FBI Information Management Division policies. At a minimum, records are maintained through one accreditation cycle. Access to records is consistent with the confidentiality commitments, and records are readily available. [ISO 17020 8.4.1, 8.4.2], [17025 8.4.1, 8.4.2]

12 REVISION HISTORY

Revision	Issue Date	Changes
00	11/08/2021	Drafted new manual, replaces the some previous QAM topics and individual LOM practices.